S. HRG. 99-948

CONTROLLED SUBSTANCE ANALOGS ENFORCEMENT ACT OF 1985

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

S. 1437

A BILL TO AMEND THE CONTROLLED SUBSTANCES ACT TO CREATE NEW PENALTIES FOR THE MANUFACTURING WITH INTENT TO DISTRIBUTE, THE POSSESSION WITH INTENT TO DISTRIBUTE, OR THE DISTRIBUTION OF CONTROLLED SUBSTANCE ANALOGS AND FOR OTHER PURPOSES

SEPTEMBER 18, 1985

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CONTROLLED SUBSTANCE ANALOGS ENFORCEMENT ACT OF 1985—S. 1437

WEDNESDAY, SEPTEMBER 18, 1985

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The committee met, pursuant to notice, at 10:17 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Strom Thurmond (chairman of the committee) presiding.

Also present: Senators Biden, McConnell, and Denton.

Staff present: Diana L. Waterman, general counsel; Frederick D. Nelson, counsel, Subcommittee on Criminal Law; and Scott H. Green, minority counsel.

The CHAIRMAN. The committee will come to order.

Senator McConnell is here and has to go to another committee, so we will yield to him.

OPENING STATEMENT OF SENATOR MITCH McCONNELL

Senator MCCONNELL. Thank you, Mr. Chairman. I just want to thank Senator Hawkins and Senator Chiles for coming by to testify today. I look forward to studying the comments made by all of you as we seek to do something about this new and difficult area of criminal activity.

So, thank you, Mr. Chairman. I must go to Agriculture. We are still trying to mark up the farm bill. Thank you very much.

OPENING STATEMENT OF CHAIRMAN STROM THURMOND

The CHAIRMAN. We meet today in hopes of forestalling a potentially grave national epidemic. Those who prosper by exploiting human weakness have discovered a relatively new field of enterprise promising huge sums of money at relatively low risk.

Increasingly, such profiteers are synthesizing enormously potent drugs which, while often lethal, are absolutely legal. Whether generated by individual back-alley chemists or by those associated with organized crime, these easily manufactured and unregulated chemical compounds present us with a truly frightening problem: designer drugs dealing designer death.

It is my earnest hope that Congress will act quickly to squash this blight. For once, we may be in a position to launch a preemptive strike and to avoid the difficulties of having to play catch-up.

Indeed, we are off to a fast start. Due to the diligence of Senators Hawkins and Chiles, who will testify today, the Senate has already held two extensive hearings that have thoroughly established the

nature and extent of the designer drug phenomenon. Moreover, the national media has been quick to detail the potential peril of this new drug wave.

Simply put, law enforcement's problem is that unlawful activity under the Controlled Substances Act is defined with regard to the precise chemical makeup of the substances described by schedules issued in accordance with the act.

Make a minor alteration in the molecular structure of an outlawed drug—replicate the chemical composition of heroin, say, in all but the slightest regard—and you have produced a powerful and dangerous narcotic that is not illegal.

These laboratory-manufactured analogs of controlled substances are imprecisely and perhaps inappropriately termed "designer drugs." Such drugs are currently being sold both as counterfeits of the drugs they imitate and for consumption as designer drugs in their own right.

As we will hear from our Florida colleagues, the Senate has already been told of the potency and potential for destruction that these drugs bring. The deaths have now begun and we are informed that in California, at least, fully 20 percent of the State's heroin addicts have turned to these even more dangerous designer compounds.

Last year's Comprehensive Crime Control Act made a start toward addressing this problem by providing for the emergency scheduling of any specific designer drug under the Controlled Substances Act.

The temporary emergency scheduling approach is terribly incomplete, however, because it is wholly reactive. To be scheduled, a drug must already be in circulation and extracting its deadly toll. Even after it has been discovered on the streets and its harmful properties diagnosed, there is a waiting period before it can be made illegal.

Fortunately, as befits the serious nature of the problem, there is a strong bipartisan resolve to give our law enforcement officers the tools needed to combat designer drugs. To that end, in cooperation with Attorney General Meese and the Reagan administration, I have joined with a number of our colleagues from both parties in introducing S. 1437, the Designer Drug Enforcement Act of 1985.

As experts in the area, Senators Hawkins and Chiles are cosponsors of the bill, as is the ranking minority member of this committee, Senator Biden. I am gratified that numerous other leading Judiciary Committee members from all shades of the political spectrum are also sponsors of the legislation.

S. 1437 would make it a crime punishable by imprisonment for 15 years and a $250,000 fine to manufacture or possess with the intent to distribute, or actually distribute, a drug intended for human consumption that is "substantially similar" either in chemical structure or in its intended effect to a compound listed in Schedule I or II of the Controlled Substances Act.

It is contemplated that legitimate chemical research will be protected both by the bill's intent standards and by the exception created for actions conducted in conformance with either an approved new drug application or an exemption for investigational use under the Federal Food, Drug and Cosmetic Act.

This hearing will probe whether any more narrow approach can fully address the designer drug problem and whether S. 1437 makes legal and scientific sense. To answer these questions and to provide us with greater information on the impending designer drug disaster, we have a most distinguished array of witnesses.

But, before I call the first witness, I wish to place statements of Senators Biden and Grassley in the record along with a copy of S. 1437.

[Aforementioned follows:]

OPENING STATEMENT OF SENATOR JOSEPH R. BIDEN, JR.

Mr. Chairman, I am pleased to join with you in holding this hearing on another very important crime bill. As the ranking member of the Judiciary Committee I believe the chairman and I have worked in a bipartisan manner to pass a number of important measures that have proved helpful to law enforcement in their fight against crime and drug abuse.

This bill entitled the Designer Drug Enforcement Act of 1985 addresses a new and expanding law enforcement and drug abuse problem that could become the drug abuse problem of the 1980's and 1990's. The enormous profits that can be made, the high potency that these drugs possess and the difficulty there is in detecting the drug could result in a drug abuse phenomenon far beyond what we have already experienced to date. The Federal Government must act quickly to stop the spread of designer drugs so that we are not caught off guard like we were in the 1970's when PCP (phencyclidine) became a major drug abuse problem.

I would like to welcome Senators Chiles and Hawkins who have been strong advocates for this new legislation. In March, Senator Chiles introduced legislation requesting a full report and strategy plan by the newly created National Drug Enforcement Policy Board on this issue. That request I believe was instrumental in the administration drafting the bill we will be considering today. Additionally, both Senator Chiles and Hawkins have held hearings on this specific subject this summer that brought to the attention of Congress and the American people the dangers and tragedy that can result from the use of designer drugs.

The real purpose of today's hearing is to consider the legislation that we all introduced in July. This new legislation will permit an immediate response to those producing designer drugs, permitting investigations, arrests and prosecution before these designer drugs spread throughout the country. I look forward to the testimony by the Justice Department and the American Chemical Society. I also understand that the Pharmaceutical Manufacturers Association will be submitting written testimony for the record.

This emerging drug problem will require a partnership between law enforcement, the medical community, and scientific community if we are to be successful in stopping designer drugs before they become the next tragic drug abuse problem in this country.

OPENING STATEMENT OF SENATOR CHARLES E. GRASSLEY

Mr. Chairman, thank you for holding this hearing on designer drugs, in order to look at the problems they produce and to examine current efforts and suggestions of what can be done to curb this insidious threat to the health of our Nation's people.

I must add my concerns that even the term designer drugs, brings with it a mystique of something new—an in thing, which can encourage unsuspecting victims to experiment with substances which are unknown and possibly deadly.

In my own State of Iowa, a growing problem with drugs exists, which concerns me a great deal. The infusion of these new synthetic drugs could dramatically exacerbate the problem. Synthetic heroin is several thousand times stronger than natural herion and much cheaper to produce. One kilogram can be manufactured for under $2,000, and the street value would be worth millions of dollars.

The clandestine production of these substances yields a number of by-products and impurities which have caused paralysis and brain damage indistinguishable from Parkinson's disease. Many of these drugs have been cut with substances such as strychnine which has resulted, among other things, in many deaths.

The phenomenon we have on our hands is a time bomb. Its consequences and dimensions could not be more frightening.

We know the Drug Enforcement Administration [DEA] has made substantial progress in controlling drug trafficking from abroad.

However, it is now possib' for one chemist to produce the equivalent of the entire world's supply of herion without ever harvesting a single opium poppy.

What used to be the province of powerful international drug syndicates, is now becoming a cottage industry. What used to take speed boats, airplanes, and so on, now takes a few test tubes, a bunsen burner, a supply of easily obtained chemicals and an empty garage.

It is because of these concerns that I have cosponsored S. 1437. We need to protect our young people from the clandestine chemists who are able to produce and distribute new chemical variants faster than they can be controlled and declared illegal.

Thank you Mr. Chairman.

By Mr. THURMOND (for himself, Mrs. HAWKINS, Mr. CHILES, Mr. BIDEN, Mr. DECONCINI, Mr. SIMPSON, Mr. COCHRAN, Mr. MURKOWSKI, and Mr. SPECTER):

S. 1437. A bill to amend the Controlled Substances Act to create new penalties for the manufacturing with intent to distribute, the possession with intent to distribute, or the distribution of "designer drugs," and for other purposes; to the Committee on the Judiciary.

"DESIGNER DRUG" ENFORCEMENT ACT

Mr. THURMOND. Mr. President, I am introducing the "Designer Drug Enforcement Act of 1985" to provide stiff criminal penalties for the manufacture, distribution, or possession of new drug substances that are dangerous for human consumption. The need for this legislation stems from popularity and abuse of chemical substances—so-called "designer drugs"—which are not currently covered by the Controlled Substances Act. This proposal will prevent underground chemists from producing dangerous designer drugs by slightly changing the chemical composition of existing illegal drugs.

The proposal combines elements of both the Controlled Substances Act and the Federal Food, Drug and Cosmetic Act in prohibiting the manufacture, distribution, and possession of dangerous designer drugs. The provisions of this bill are directly tailored to apply to this new drug problem, and specifically defines designer drugs to cover those substantially similar to existing controlled substances.

This act will be extremely important to law enforcement officials in the continuing battle against drug abuse and drug trafficking. It is my hope that we will be able to act upon this important and noncontroversial legislation as expeditiously as possible. The administration, and especially Attorney General Edwin Meese, is to be commended for developing this important remedy to a growing national problem.

Mr. President, I ask unanimous consent that the remarks of my colleagues, Senator HAWKINS and Senator CHILES, be included in the RECORD at this point.

In addition, I ask unanimous consent that a copy of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1437

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "'Designer' Drug Enforcement Act of 1985".

SEC. 2. Part D of the Controlled Substances Act is amended by adding after section 403 the following new section 403A (21 U.S.C. 843):

"Sec. 403A. Prohibited acts D.

"Any person who knowingly or intentionally manufactures with intent to distribute, possesses with intent to distribute, or distributes a designer drug intended for human consumption shall be fined not more than $250,000, or imprisoned not more than fifteen years, or both. This section does not apply to a person who manufactures or distributes a substance in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). For purposes of this section, section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be applicable to the introduction or delivery for introduction of any new drug into intrastate, interstate, or foreign commerce.".

SEC. 3. Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end thereof the following new paragraphs:

"(31) The term 'designer drug' as used in section 403A means a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedules I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedules I or II. Examples of chemical classes in which designer drugs are found include, but are not limited to, the following: phenethylamines, N-substituted piperidines, morphinans, ecgonines, quinazolinones, substituted indoles, and arylcycloalkylamines.

"(32) The term 'human consumption' includes application, injection, inhalation, or ingestion.".

SEC. 4. The analysis of Part D of the Controlled Substances Act is amended by inserting after the item relating to section 403 the following:

"403A. Prohibited acts D.".

Mrs. HAWKINS. Mr. President, I am proud today to cosponsor legislation designed to outlaw designer drugs.

This comprehensive proposal will make illegal any substance that is similar in molecular structure to a currently illegal drug or any substance that simulates the high of a currently illegal drug. This bill would add a new section to the Controlled Substances Act, as at present unlawful activity under that act is tied to the description of substances in various "Schedules." Heroin, for example, is a "Schedule I Narcotic" because it has no accepted medical use and because it causes adverse health effects. This legislation would carry a punishment of 15 years imprisonment, and a fine of $250,000.

Mr. President, when designer drugs have so far killed over 100 people on the west coast; when designer drugs have caused a near epidemic of Parkinson's disease among their users; and when designer drugs are responsible for an entire new type of destructive narcotics abuse, then it is time to take the necessary steps to put a stop to them. With this legislation, we are taking the first of these steps.

At first thought to be a west coast phenomenon, designer drugs are now considered to be a very real danger to the entire Nation. Clandestine laboratories are being discovered in places like Brownsville, TX, and Phoenix, AZ, as well as in my home State of Florida. Federal drug law enforcement officials are increasingly concerned at their powerlessness to stop the creators of designer drugs, as what most often happens is that the chemist will make minor changes in the molecular make-up of the drug, thereby making legal a substance just designated illegal by drug law enforcement agencies.

Mr. President, with this legislation, we will now be one step ahead of these high tech killers, instead of one step behind. In our war against drugs, we are constantly faced with new and more devious diversions. This is a war with a front that is constantly changing. As the designer drug manufacturers roll out new weapons, we must be prepared to striked back with new,

legal weapons of our own. I feel that this proposal provides us with the effective new weapon we need to fight against designer drugs.

As chairman of both the Senate Subcommittee on Children, Family, Drugs, and Alcoholism, and the Senate Drug Enforcement Caucus, I am well aware of the wholly new nightmare of problems designer drugs create. Just consider the following: Designer drugs' formulas can be found in almost any university chemistry library designer drugs can be made in undetectable bathroom-size laboratories, beyond the reach of customs officers and eradication teams; from $500 worth of chemicals, an individual can make $2 million worth of one specific kind of designer drug, synthetic heroin; one laboratory can meet the world's demand for heroin like drugs without harvesting a single opium poppy; fewer people need to be "cut in on the action," so the profit margin is higher; and, as we have discovered, as fast as the Government outlaws designer drugs, the chemists can synthesize new ones. For these reasons, designer drugs have become so popular that it is now estimated that 20 percent of California's 100,000 heroin users are now taking one of them.

Mr. President, the "designer drug" bill just introduced in the Senate will allow us to address some of these aspects of the problem, and will enable us to tackle the difficulties of the designer drug situation before it rages out of control. I commend my friend and colleague, Senator STROM THURMOND, for his sponsorship of this legislation, and urge my colleagues in the Senate to work toward this bill's expeditious passage.

Mr. CHILES. Mr. President, I am delighted to join in introducing the Designer Drug Enforcement Act of 1985 proposed by the administration. The administration, through the efforts of the National Drug Enforcement Policy Board, has been very timely in addressing this issue. Earlier this year I introduced S. 746, a bill to require the National Drug Enforcement Policy Board to provide a comprehensive assessment of the designer drug problem and make recommendations to Congress for necessary legislation. At a hearing of the Senate Appropriations Subcommittee on Commerce, Justice, State, the Judiciary, and Related Agencies earlier this year, I secured a commitment from Attorney General Meese, as Chairman of the National Drug Enforcement Policy Board, to address the designer drug problem and develop a strategy to get the necessary laws on the books before the problem gets out of hand. This bill meets that commitment. We cannot overstate the dangers posed by these new drugs. We need concern and results, and I certainly commend the Attorney General for his quick handling of this.

Last March I brought the designer drug problem to the attention of my colleagues. This bill addresses the problem by making it unlawful to manufacture with intent to distribute, to possess with the intent to distribute, or to distribute designer drugs. Persons convicted of manufacturing, possessing or distributing would be subject to 15 years imprisonment and a $250,000 fine.

Designer drugs are made by chemically modifying controlled substances to produce analogs or chemical cousins of these substances which are not covered by the Controlled Substances Act. By adding a flouride or an extra carbon molecule, a new drug is created which will produce the high or euphoria the user seeks but is not illegal. But they are extremely dangerous, thousands of times more potent than the illegal narcotics presently flooding the country, and nearly a hundred deaths have been identified with designer drug use so far.

The more commonly used drugs—cocaine, heroin, and marijuana—takes a terrible toll on their users in health problems and even deaths. Designer drugs multiply these risks and open the door to long term neurodegenerative diseases, adding an entirely new dimension to the drug abuse problems. No one knows what is in each batch of designer drugs. They are not tested; there is no process to remove contaminants or unwanted compounds; and the potential is very real that a highly toxic compound will hit the streets. In California a substance known as MPTP was circulated as new heroin. It has caused severe brain damage similar to end-stage Parkinson's disease. California health authorities estimate that as many as 500 users of this substance may develop the symptoms of Parkinson's disease. The human and medical economic costs of such an epidemic are almost incalculable. More recently, a designer drug user has been identified with the neurological symptoms of Huntington's chorea, a debilitating and eventually fatal disease.

All the signs indicate that designer drugs will be a major part of the drug abuse problem of the future. If that proves to be the case, the public health consequences of drug use may be entering an entirely new and frightening dimension.

The current procedure for controlling illicit drugs, even with the emergency scheduling provisions authorized by Congress in 1984, represents an essentially unworkable response in the face of any significant increase in the manufacture of designer drugs. The Federal Register will simply be required reading for the criminal chemist to keep up to date on what analog formulas are now illegal and need to be modified.

Mr. President, our experience with illegal drug law enforcement is usually a matter of too little, too late. The potential disaster posed by the designer drug phenomenon is too grave for us to delay in acting to prevent the manufacture and distribution of these drugs. This bill needs our immediate consideration.

The CHAIRMAN. Our first witnesses this morning are Senator Hawkins and Senator Chiles. Do you have a preference as to who goes first?

Senator CHILES. Senator Hawkins.

The CHAIRMAN. Senator Hawkins, you have done a great deal of work on the drug problem and I just want to take this opportunity to publicly commend you for all the fine work you have done, which I think is of great benefit to humanity.

You may proceed.

STATEMENT OF A PANEL CONSISTING OF HON. PAULA HAWKINS, A U.S. SENATOR FROM THE STATE OF FLORIDA; AND HON. LAWTON CHILES, A U.S. SENATOR FROM THE STATE OF FLORIDA

Senator HAWKINS. Thank you, Mr. Chairman. I would like to thank you for this opportunity to testify today on probably the most important——

The CHAIRMAN. If it is agreeable to you all, could each witness summarize his or her remarks in 5 minutes and put the rest in the record?

Senator HAWKINS. Surely.

The CHAIRMAN. We have so many witnesses today, we must unfortunately restrict all of them to that time limit.

Senator HAWKINS. A very important hearing today, Mr. Chairman, and I too have to be in Agriculture, which Senator McConnell just left to go to.

The subcommittee I chair—Children, Family, Drugs and Alcoholism—investigated this growing drug abuse phenomenon in late July, and what we discovered about the potential impact of this newest illicit narcotic problem is horrifying.

Drug abuse is responsible for lowered national defense, impaired productivity, failed education, increased violent crime, corruption, addiction, and death. Until recently, the sources of the illicit narcotics that cause these devastating societal problems have been poppy, coca, and marijuana grown in foreign fields.

We have tried to cut off these sources in order to stop producing nations from cultivating and marketing their crops. We have been interdicting these drugs before they reach our shores and we have been using the military in conjunction with local law enforcement.

Now, we are confronted with an entirely new problem. Sophisticated chemists are creating synthetic heroin, synthetic cocaine, and numerous other kinds of narcotic analogs in clandestine laboratories with minimal cost and effort all over the United States. These synthetic drugs are proving to be even more destructive than their parent plants. They are nothing less than high-technology killers.

In laboratories originally just on the west coast, but now found all over the United States, outlaw chemists are taking $50 worth of materials found in any hardware and pharmaceutical store and, with it, creating 100 million doses of synthetic narcotics.

These drugs bring about the same high, the same addiction and the same death as natural narcotics, but with much greater potency. Numerous drug abusers in California discovered how potent;

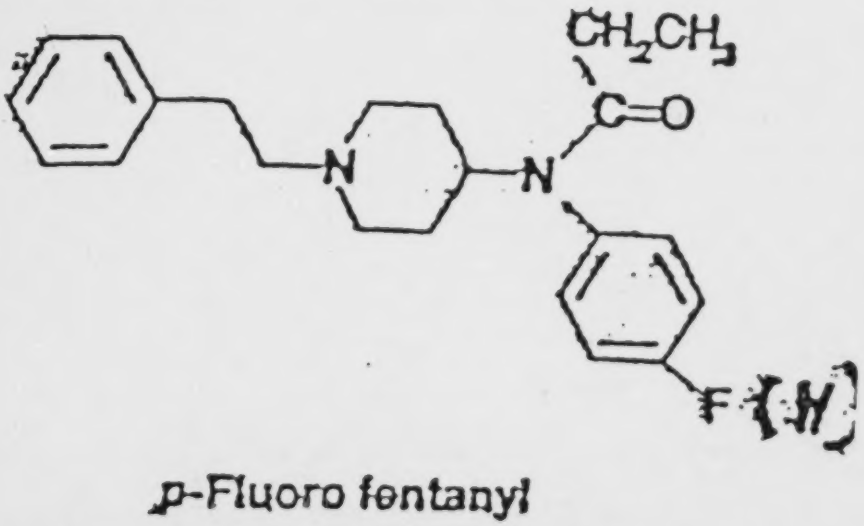
over 100 people have died so far in California from taking synthetic drugs.

These drugs have also been the cause of a near epidemic of Parkinson's disease on the west coast. One of these drugs, a fentanyl derivative, has been found to be responsible for a large number of cases of Parkinson's disease, an incurable neurodegenerative affliction.

I would like to demonstrate for you, Mr. Chairman, just how easy it is to create this legal poison from illegal drugs. This is a model of a fentanyl molecule. Fentanyl is a synthetic narcotic, a schedule II narcotic, if you will. It is similar to morphine and opium.

The ball at the end of the molecule represents a hydrogen atom. In order to create a completely legal form of this drug, the chemist merely removes the hydrogen atom and replaces it with a florine form. The result is fluorofentanyl, completely legal and just as deadly.

[Model of fentanyl molecule follows:]



p-Fluoro fentanyl

Senator HAWKINS. Since the law dealing with narcotics control defines illegal drugs by their exact molecular structure, the creators of these drugs simply have to alter their product slightly as soon as it is made illegal by the Drug Enforcement Administration.

What is now taking place in this new system of narcotics productivity is that by the time scientists decipher the structure of the chemist's latest product and our enforcement agencies take steps to outlaw it, the manufacturer simply redesigns the molecule.

Synthetic drugs are a whole new class of killers supplying a whole new set of victims. The potential cost to society of this growing national problem is staggering, and this is something on which we all agree—law enforcement officials, treatment authorities, and legislators alike. This rapidly increasing problem has been called the drug wave of the future and needs a coordinated effort from all quarters to combat it.

I would like to provide some examples of the kinds of situations we have to deal with. The cost of production is so low that for $2,000, millions of doses of synthetic drugs can be created.

These doses can be sold by a dealer for $100 or for $1 and they would still be making a profit because there is no middleman. The synthetic drug operation is still in the hands of small entrepreneurs rather than under the control of organized crime.

The potency of synthetic drugs can be as much as 1,000 times greater than that of the parent plant. For example, 3-methylfentanyl has been cited as being 1,000 times stronger than heroin.

Almost no testing procedures exist in treatment and/or rehab centers in the United States for any of these substances like fentanyl and MDMA, so practically no treatment directed at synthetic drug abuse exists.

This is a uniquely American problem, with misuse of American technology responsible for the unconscionable crime of synthetic drug trafficking. We need to take steps to keep the synthetic drug problem from becoming the catastrophe that it promises to be.

The law enforcement community, the medical community, the education sector, and private industry can all be called upon to stop the problem before it starts. For these reasons, Mr. Chairman, I am pleased to see you taking quick action in addressing this situation.

S. 1437 takes a very large step in initiating the process of eradicating the problem of synthetic drugs in our Nation. This proposal provides the enforcement power that is needed to clamp down on those who traffic in synthetic drugs. I was proud to be an original cosponsor of this far-reaching proposal and will certainly continue to work alongside you to ensure its expeditious passage.

You always exhibit the very special qualities of leadership, Mr. Chairman—quick action in addressing the needs of the American people. And sitting beside me on this first panel today is another individual who should be praised for his leadership in the area of synthetic drug abuse prevention—my esteemed colleague from Florida, Senator Lawton Chiles.

Senator Chiles was one of the first members of the U.S. Congress to recognize this situation as a growing and intolerable problem and he has never wavered in his dedicated effort to eradicate synthetic drug abuse in our Nation. With the effective and concerted effort of leaders such as you and Senator Chiles, I feel we really can have an impact on synthetic drug abuse.

In closing, Mr. Chairman, I would like to make a personal observation. Perhaps you have noticed and your staff has noted that nowhere in my testimony did I employ the popular usage for synthetic drugs, the so-called designer label. I would hope that this highly erroneous and misleading term will be dropped in referring to synthetic drugs, as it gives a false impression of something desirable and something trendy, something that really ought to be sampled because it may be fashionable.

Youthful demand for illicit narcotics can be started for such tenuous reasons and the end result can be devastating. So let us take away one of these tenuous reasons by calling these high-technology killers what they are and no more—call them synthetic drugs.

Thank you, Mr. Chairman, for this opportunity to be helpful in this docket.

The CHAIRMAN. Thank you very much.

I thought we would hear from Senator Chiles and then I would call on Senator Biden for a statement.

Senator Chiles, I want to commend you for your outstanding leadership in this field, and we are very pleased to have you come and testify here this morning. We would be glad to hear from you.

STATEMENT OF SENATOR LAWTON CHILES

Senator CHILES. Thank you, Mr. Chairman. I am delighted to appear before this committee, which has done so much to try to help us combat drugs. I think your committee now has before it a rare opportunity, and that is an opportunity to address this terrible problem before it becomes a national disaster.

I am talking about designer drugs and the glitch in our law which allows those with only a smattering of ability to produce a deadly chemical in their basement and sell it—entirely legally—on the streets of America.

We have spent millions of dollars in the last decade in combating, with some success, the importation of deadly drugs. You, Mr. Chairman, and your ranking member, Senator Biden, have been at the forefront in putting forward legislation to combat that problem. We certainly need to continue the funding for that.

Now we're finding that unscrupulous drug dealers are buying equipment and chemicals over the counter and producing—again, quite legally—the same kinds of substances we have been spending millions of dollars to keep out of America.

The key here, Mr. Chairman, is the same kind of substances and it is that key which the present law does not address. I held hearings on this problem in July and heard story after story about how these basement chemists could, and did, stay one step ahead of the law in California; how they could produce a deadly chemical for up to 2 years before the California Legislature had the time to declare that specific chemical combination illegal.

Of course, with the criminal enterprise that these basement chemists had displayed in producing this drug to begin with, they had only to tinker once more with the recipe and then cook up another drug, as Senator Hawkins has displayed; this one with the same desired effects, but this time, again, legal.

Then, the same time-consuming legislative morass had to be waded through again, wasting time and Lord knows how many lives, before this particular chemical was outlawed.

A mother and father from the Washington suburbs testified at my hearing of the ease with which their son legally and easily bought the necessary equipment and chemicals from Washington, DC, supply houses and then just as easily made designer drugs on top of the family washing machine in their basement laundry room.

They also testified about what these drugs had done to their son and the horrors of seeing him with a Parkinson-like syndrome, and about the money they spent on psychiatrists and research physicians.

Mr. Chairman, they testified about the State police coming to their home during the night to tell them that their son had been found dead, a victim of drug overdose. Their horrors and their son's horrors are perhaps new to us, but they are being experienced many times everyday in this country.

Mr. Chairman, I would like to show you a short videotape made in California by Dr. William Langston about the Parkinson-like syndrome which many of these takers of designer drugs develop.

The CHAIRMAN. You may proceed with that.

Senator CHILES. Thank you, Mr. Chairman.

These patients that we are about to see were starting out on L-dopa out of desperation. This is the same drug used to treat Parkinson's patients.

The young man that we are going to see first is absolutely frozen halfway out of getting out of bed. He had used designer drugs for approximately 2 weeks with his brother until the point that they could no longer move, and they probably would have starved to death had it not been for their mother, who stopped by the apartment in which they were living to see them.

You can see the complete loss of facial expression; his voice is diminished. This young man was very athletic, sort of a jock, before using these drugs.

Now, I am going to show you a young woman who was completely frozen; she was unable to move for 6 weeks before being treated with L-dopa. After treatment, she has her facial expression back; she can smile. The medication probably saved her life; she would have died without it. You see she is able to move now.

Now, I am going to show you 5 minutes later; you will see the side effects of the medication. You see the twisting and writhing movements that she has. She has now lost 50 pounds because of those movements, which are uncontrollable. You usually don't see this side effect with L-dopa until at least 5 years' use in classic Parkinson's cases. Of course, normally you get Parkinson's disease at 60 years of age or older. She got the side effects within 3 weeks, so you can see what her history is going to be.

The other problem is the wearing-off effect. The medicine works for shorter and shorter periods of time. This film would be at 2 p.m. and the patient had received his medication. This is 4:22 p.m., 2½ hours later, and if you will notice, he is acting completely normal; he is able to sort of do some calisthenics.

Now, this is less than 20 minutes later and you are beginning to see the drug wear off. It is like seeing Parkinson's evolve in front of your eyes. This young man, as I told you, was an athlete. He has been exercising; he is now trying to exercise, but you notice that he is already slowing down. This fellow had about 2 hours' relief with a dose of the drug and now his body is locking him back again.

Now, this is 9 minutes later. He is completely unable to move. The only thing he can move now is his eyes. He says, "I cannot move." Mr. Chairman, he now has to take this medication every hour and 45 minutes to be able to move at all, and there is a very progressive course as to what the side effects of this drug begin to do.

So the doctors are not optimistic about the future of a number of these patients because of the problems they are having. The human body just cannct last very long in this condition.

The doctors are aware of over 400 young people who used these drugs in northern California. Although most of them are currently asymptomatic, a senior investigator at NIH has referred to them as walking time bombs; any time, any one of them could go into this Parkinson-type problem.

Of course, the horrors we have just seen are not going to deter those basement chemists from their tasks. They will not stop as long as they can spend $2,000 on equipment and chemicals, and turn 2 weeks of time into 200 million doses of drugs which have a potential street value of $70 billion.

No, they are not going to stop if what they are doing is not declared to be illegal, and that, Mr. Chairman, is the essence of my testimony. We have got to make it illegal. My own State of Florida is already working in the legislature and in the medical community to acquaint themselves with the potentials of these designer drugs.

Florida's medical examiners know that there have been over 100 reported deaths nationwide from these drugs, and they realize that there have probably been 100 times that many because the expertise to detect a death from these designer drugs is simply missing from most coroners' offices.

A statewide meeting of medical examiners in Florida next month will focus on these drugs, as medical examiners and law enforcement officials try to get ahead of the curve and try to stop the phenomenon of designer drugs before it gets to the disaster stage.

That, Mr. Chairman, is what Congress must do. We have to outlaw these drugs before the country finds itself in the middle of a national health disaster of overdose deaths, poisonings, and addiction.

I thank you for the opportunity to testify before you. I want to send up this little vial. If you look at the very bottom of this, you are going to see a little speck, a little white speck, on the bottom. That will show you the amount of designer drugs that it takes to kill somebody.

In fact, these drugs are so powerful that that speck of material you are looking at on the bottom, which is a potentially lethal dose—you could make 200 doses from that speck. You can cut that into that kind of proportion and make 200 doses from that.

It is just mind-boggling, the terrible sort of monster that we have here.

Senator BIDEN. You mean that one speck I am looking at, which is not much bigger than a pin head—that speck, if I put that on my tongue, could kill me?

Senator CHILES. That is a lethal dose and it also could make potentially 200 doses, cutting it with some other substance which they would mix it with. If they sold that to you on the street, you would not know it from China White which is one of the purest forms of heroin.

Now, again, had they overcooked it a little bit or undercooked it or done anything—and these fellows do not have any basic con-

trols—that is where you get these horrible side effects from the drugs.

Senator BIDEN. Thank you.

Senator CHILES. Dr. Henderson at our hearing said that I could smuggle enough fentanyl soaked into the tab of my collar to supply this room for quite a while. In fact, he said I could do the same thing by smuggling that much under a postage stamp.

At our hearing, we had a pretty good, full room. He said I could supply the whole room with what I could put into the tab of a collar or put under a postage stamp.

The CHAIRMAN. Senator Chiles, I want to thank you for your excellent testimony and, again, I want to commend both you and Senator Hawkins for the outstanding leadership you have provided in this matter. I am sure that your work will be of great benefit to this Committee.

When this bill passes, I am sure that it will be of great benefit to people everywhere. Thank you very much.

Senator Biden.

STATEMENT OF SENATOR JOSEPH R. BIDEN, JR.

Senator BIDEN. Thank you, Mr. Chairman. I apologize for missing part of Senator Hawkins' testimony. I have been demanding a hearing in the Foreign Relations Committee; they finally gave it to me. It is on extradition and I am going to have to go back up to it after this, but hopefully I will be able to come back down.

I have two questions for you, Senator. First of all, obviously, as your colleague and everyone else has pointed out, you are the one responsible for bringing our attention to this issue.

I know when I was requesting a hearing on this subject and the Chairman was moving forward with it in the spring, you had introduced your bill already, S. 746, which requires a complete report from the National Drug Enforcement Policy Board—the so-called drug czar, chaired by the Attorney General.

That report came out in July 1985, after you had already made the request. I wonder if you would tell me whether the report met your expectations? I guess that is the best way to put it without asking all the technical details.

Senator CHILES. Well, let me say that I have publicly, and I do so again, complimented the Attorney General and the Justice Department for the speed with which they came forward with a bill on designer drugs.

I asked the Attorney General at a hearing we had at State, Justice and Commerce if he recognized the potential danger of this and cited to him the legislation that I had introduced. And they worked very, very quickly, and that is the bill that we have before us. I certainly compliment them.

To go back to your specific question, the five paragraphs which constitute the entirety of the Board's comments are somewhat inadequate. The concluding statement that, "The Board will regularly monitor changing situations in drug enforcement such as this to be alert to the need for changes in policy," does not strike me as an aggressive approach to preventing the designer drug phenomenon from becoming this nation's next drug tragedy.

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If I understand the purpose of the National Drug Enforcement Policy Board correctly, it should be, and it was to be, developing a comprehensive strategy to get us ahead of the curve on designer drugs. The hearing I chaired made clear that we face this difficult task, and I will tell you I do not think that monitoring the situation or submitting a draft bill is sufficient.

Now, I want to point this out: This bill should be enacted as quickly as we possibly can. But I do not think we could then pat ourselves on the back and say we have taken care of the designer drug problem, when this can be done in anybody's basement and we are talking about a minimum amount of $2,000 to get in business and produce up to $70 billion. Passing a law, you know, does not cure that problem.

I think we need some kind of massive program—education, promotion—trying to get parents, educators, law enforcement people, coroners, medical people together to recognize what we just saw; what the potential Frankenstein horrors are with these drugs.

So I do not think we can depend on just a law or just the law enforcement community. I think this really has to go to the demand situation that we really still have not touched properly in this country, and alert people about what the real dangers are here, alert communities, alert local police and local coroners and try and get in front of this.

Senator BIDEN. I guess being optimist is, as the Chairman well knows better than any of us, an occupational requirement for all of us to have this job. But I really think what you have called to our attention and what is becoming more apparent might be a way that we can make some inroads into the whole drug problem.

Quite frankly, in the Foreign Relations Committee we had hearings on the drug czar and looking at it from the side of international drug trafficking. One of the things the Attorney General said and I know the Chairman feels strongly about is that there seems to be an increased understanding of the need to educate the population as to the dangers of drugs and you have to deal with the demand side.

Senator CHILES. Right.

Senator BIDEN. Quite frankly, I think if we were willing to not only spend money but be imaginative in terms of our ability to present to our young population the potential side effects of these drugs, it may have a very sobering impact, but it is going to take a significant and concerted effort.

Let me just end by saying one thing. There is a big difference between 1966, when I was a law student and we use to have these forums where we would go around from the law school to the high schools, and talk about law.

I will never forget being on a panel in Syracuse, which is where I went to law school, at a high school assembly. Also, on the panel was a man who was suppose to be an expert on drugs and he was talking about marijuana.

To this entire assemblage of 1,800 or 1,900 high school students, he started to tell them about how, if they smoked marijuana, it would make them blind and sterile and they would have acne and, you know, all this malarkey.

I think we went through a period of time when we oversold the side effects that we could not prove. There is no question that marijuana is a health hazard; there is not any question at all anymore, but it does not cause blindness and acne.

So when these kids would go out there and they would see it and they would use it, they would say, well, my friend uses it and it does not happen to him.

We went overboard the other way and said there was no problem. I think we have gone, unfortunately, full circle.

That is a devastating piece of film that you have shown and I cannot imagine that we cannot take what you have started and really do something very positive besides passing the law here.

I hope we in the Congress, as you said, once we pass this law, and I believe it will be passed expeditiously, do not think that, since we have a new tough law and everything is all right.

I really compliment you. There are few times that a Senator has an opportunity in his career to bring the attention of the Nation and to his colleagues for purposes of constructive action on a serious problem and be able to do something serious about it. It is a heck of a job you have done.

Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Chiles, do you not think it might be helpful if every high school in this country and every junior high school could get films and show them to the students and educate our young people on the terrible dangers of these drugs?

Senator CHILES. Very much so, Mr. Chairman, and I think Senator Biden puts his finger right on the point. There were times that we did not know what we were talking about when we talked about side effects of drugs, and the kids got where they did not believe us or we lost our credibility.

On the other hand, where we really have been able to show them potential birth defects and other things from drugs, they have responded. If you notice, there are certain of the mind-altering drugs that they are very careful about now, and that, I think, with the potential of designer drugs, is something that definitely we need to do.

It is going to take some kind of a coordinated effort to do that and I certainly look forward to working with you and others in attempting to try to see how we can do that.

The CHAIRMAN. Do you not think it would be helpful, too, if we could get the different TV channels in this country to run programs on this subject for the benefit of all of the people?

Senator CHILES. Yes, sir; I think it would. I think there has been quite a bit of publicity in regard to designer drugs and the potential harmful effects. But, again, I think it is something that an awful lot more needs to be done.

The CHAIRMAN. Thank you again for your splendid testimony.

Senator CHILES. Thank you.

The CHAIRMAN. Senator Denton, do you have any questions you want to propound?

OPENING STATEMENT OF SENATOR JEREMIAH DENTON

Senator DENTON. Well, Mr. Chairman, I just want to express my gratification that you have brought this bill forward. I want to compliment Senator Chiles and emphasize that as one Senator I am aware of how totally bipartisan this approach to the designer drug phenomenon has to be.

Senator Biden has been a leader in this before my arrival at the Senate and has helped me tremendously in the oversight of the Drug Enforcement Administration. You, Mr. Chairman, are as diligent and persevering as anyone on this problem.

The House-Senate conference on Armed Services, believe it or not, dealt a lot with the drug problem. We are committing tremendous resources to the drug problem but not with tremendously gratifying results. Now we have this designer drug problem which kills and cripples our Nation's youth in increasingly greater numbers.

We do have to take all the steps that you have mentioned, Mr. Chairman. I understand that these drugs are mainly found in California. I would like to know from Senator Chiles whether designer drugs have surfaced in Florida? How much of this do you have down there, and if quite a bit, do you have in mind efforts to capitalize on this experience that you have gained in Florida so that it can be shared with other Federal, State and local law enforcement agencies as they come to face the designer drug problem?

It is phenomenal to me to learn that this tiny little speck of China white which you have passed around can make so many doses. It is just incredible.

Senator CHILES. Yes, sir.

Senator DENTON. How would you propose to spread the warning about the danger of designer drugs to each State and around the country?

Senator CHILES. Well, to answer the first part of your question, this started in California. We still think that the greatest incidence is in California, but there is evidence of it spreading.

As of the time we held our hearing, and I assume there probably has not been any change, in California the organized drug people were not into this. It was sort of a new wave of the chemists that were into this.

But the interesting thing is, how long is it going to take before organized crime gets involved—and the reason they are not in it is because they have their existing supply lines and, they are used to doing business that way.

In fact, some of the labs were knocked off by organized crime people because of the competition. The question is, given how simply you can do it and that you do not have to worry about the Coast Guard or the Air Force or somebody trying to interdict you in getting your supply in or a host country stopping it before you get it out—that is why I think it is so important that we try to pass this law before we have this happening.

The other problem is the detection of these drugs is very hard. It was a long time before, in California, they began to see these drug overdose deaths. When they did an autopsy, it did not seem to be

quite like the normal overdose death, but they did not know what they were looking at.

It took a while and then they began to realize that fentanyl had been used in doping racehorses and they began to sort of look and find that they had to change their techniques entirely to be able to detect this.

Now, in Florida, we are holding a big conference now with coroners and law enforcement officers. We have some deaths down there that do not fit the normal pattern, but at the time those autopsies were done we were not looking for designer drugs.

So we think we may already have had some deaths attributed to designer drugs but we did not have the right kind of examination at that time. We need an across-the-country effort to get law enforcement people together with the medical authorities, the coroners and all, so they can begin to make the right tests, ask the right questions, look for the right things to determine how far this has spread.

We know it is greater than California; we do not know to what extent however. Your law enforcement people will tell you more about that.

Senator DENTON. You anticipated my next question. I gather that you do think it is only a matter of time before organized crime moves in and takes over the designer drug market.

Senator CHILES. Absolutely. That is why I think it is so important, as the Chairman said, that we get the information out there to young people of what the terrible side effects of these drugs are.

Literally, somebody who thinks that they have been able to buy heroin before and deal with that better be concerned because they will not be able to tell the difference at all as they sample it or taste it or try to purchase it, and they may well be buying one of the designer drugs.

Senator DENTON. Well, thank you, Senator Chiles.

Senator CHILES. Thank you.

Senator DENTON. Mr. Chairman, I assure you of my utmost support and cooperation in moving this legislation. I have to leave, but I will leave some questions and ask that they be submitted to the other witnesses, Mr. Chairman. Thank you.

The CHAIRMAN. Thank you very much, Senator Denton. I know of your intense interest in this subject and all you have done to combat it.

Our next witnesses are a panel consisting of Stephen Trott, Assistant Attorney General for the Criminal Division of the Department of Justice, and Gene Haislip, Deputy Assistant Administrator of the Drug Enforcement Administration.

Gentlemen, you and the Attorney General have our gratitude for the timely and responsible fashion in which the Reagan administration has addressed this problem.

Mr. Trott, your full statement will be placed in the record. Could you please give us a summary of your testimony in not over 5 minutes?

STATEMENT OF A PANEL CONSISTING OF STEPHEN S. TROTT, ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION, U.S. DEPARTMENT OF JUSTICE; AND GENE HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

Mr. TROTT. Thank you, Mr. Chairman. I will be very pleased to do that especially since you have already spoken, as have the other witnesses, so eloquently as to the frightening dimensions of this problem and to the need for immediate action in terms of legislation.

Let me move then directly into a discussion of the bill that is before you. Department of Justice attorneys, chemists, and regulators, as well as Department of Health and Human Service officials, considered several issues in the development of S. 1437.

The major hurdles that have been overcome by this bill are the need to protect legitimate scientific research while effectively proscribing activity involving dangerous, alternate drugs. Of course, we are also departing from the original, basic approach of the Controlled Substances Act that relies on the scheduling of substances before activity involving them is prohibited, and finally, of course, we are intermeshing two disparate statutory schemes.

As we believe and as you have noted, current law is simply inadequate to deal with this problem. Let me talk briefly, then, about the need to protect legitimate scientific research and assure you that that has been done by this bill.

While a statute which effectively combats the designer drug problem must address a range of activities, including the manufacture of these substances, such a statute must also protect legitimate scientific research; that is, chemists should be free to conduct legitimate experimentation without fear of committing a serious Federal felony.

S. 1437 includes several features designed to protect legitimate scientific research and to assure that the proposed statute is not over broad. First, it should be noted that the bill relates only to those substances which are substantially similar to controlled substances in schedules I and II. This limitation was included because the most serious problems to date have involved substances which are similar to drugs in one of these schedules. Next, the bill proscribes the manufacture with intent to distribute designer drugs, the possession with intent to distribute them, and the distribution of such substances only if they are intended for human consumption and only if the proscribed activity is knowing or intentional.

Therefore, a laboratory chemist who experiments with molecules in an attempt to develop a new industrial chemical would not be affected by the proposed statute. One who experiments in the development of a drug for legitimate medical use—specifically, for human consumption—may have to consider the dictates of the bill, but could easily avoid becoming enmeshed in its proscriptions.

The bill provides an exemption mechanism tied to the new drug approval process of the Federal Food, Drug and Cosmetic Act; that is, activity regarding legitimate, new drugs is protected by the bill's exemption for manufacturing and distribution of a substance in conformance with the new drug approval provision of the Federal Food, Drug and Cosmetic Act, and early-stage research activity is

protected by reference to the exemption from the new drug approval requirement for investigational use in title 21, United States Code, section 355.

By the way, I agree with Senator Hawkins that there may be a danger in continuing to call these substances designer drugs. We know what we are referring to, and we know it is dangerous. But the term "designer" may send a different message to people out there, especially young people, and it might be productive to look in the bill itself for other language that conveys the dangerousness of the problem.

In essence, we have defined the problem as including substances that are substantially similar to controlled substances already in schedules I and II. The definition in S. 1437 provides a two-prong approach to this drug problem. A prosecution must be based on a substantial similarity in either chemical structure or effect between the substance in question and a schedule I or II controlled substance.

We think this simply presents a question of fact that can be adequately coped with in court in any prosecution that ensues. This is a scientific exercise that is accepted by the scientific community, and I am told by chemists at DEA that the "substantially similar" definition is one that can be adequately addressed by chemists in the context of questions of fact.

Expert testimony by chemists who perform laboratory analyses would be the basis for establishing the nature and degree of similarity when the chemical structure of the substance is in issue.

In essence, Mr. Chairman, that is a summary of the testimony that we have submitted in a 16-page document and, in the interests of time, I would now offer the testimony of Mr. Haislip in this connection or answer any questions that you might have regarding the specific content of this bill.

[Statement follows:]

Statement

of

STEPHEN S. TROTT
ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION

Chairman Thurmond and Members of the Committee:

I appreciate the opportunity to appear before you to address the need for legislation to combat the problem of designer drugs, and in particular to discuss S. 1437, which was developed by the Department of Justice and the Drug Enforcement Administration through consultation with the Department of Health and Human Services.

Designer drugs -- drugs which are similar in their chemical structure or effect to Schedule I or II controlled substances -- have become a significant law enforcement problem. Sophisticated experimentation by chemists intent upon evading the law has led to the development of these new drugs which are as dangerous as controlled substances or in some cases even more hazardous because of their increased potency and unusual side effects. However, these drugs are sold and used before they are included within the schedules of substances subject to the Controlled Substances Act and, thus, are not subject to this statute. As a result, the designer drug phenomenon serves the drug dealer's dual purpose of circumventing the existing drug laws and reaping huge profits because of the relatively low cost of manufacture as compared to the cost of obtaining illegal substances. In a recent statement before the Subcommittee on Alcohol and Drug Abuse of the Committee on Labor and Human Resources, DEA Administrator John Lawn presented valuable information on the dangers of designer drugs and explained that the problem is not new. In fact, the enactment of the Controlled Substances Act in 1970 was in part a response to the problem of then popular designer drugs, such as MDA and MMDA, which are hallucinogenic amphetamine analogs of mescaline. Statement of July 25, 1985.

S. 1437 would provide the legislation needed to combat the

problem of designer drugs by adding a new section 403A to the Controlled Substances Act to create penalties regarding these substances. The proposed provision makes it unlawful to manufacture with the intent to distribute, to possess with the intent to distribute, or to distribute designer drugs intended for human consumption unless such action is in conformance with section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §355, regarding new-drug approval. Specifically, the term "designer drug" is defined for purposes of the proposed provision to mean a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedules I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedules I or II.

Current law is inadequate to deal with the phenomenon of designer drugs. Unlawful activity under the Controlled Substances Act is tied to the description of substances in the schedules of controlled substances issued under the Act. Thus, if a particular substance is not included in one of the schedules, it is not unlawful to manufacture or to distribute it without complying with the Act's registration and other requirements, despite the potential for abuse created by the substance. However, the scheduling process is time-consuming because the Controlled Substances Act, 21 U.S.C. §811(a), requires that it be accomplished through a rule making procedure on the record after opportunity for a hearing, as prescribed by the Administrative Procedure Act. Authority recently provided by section 508 of the Comprehensive Crime Control Act of 1984 for the emergency scheduling of substances on a temporary basis addresses this problem and reduces the potential for abuse to a great extent. 21 U.S.C. §811(h). However, it does not eliminate the problem because a significant period of time may elapse before DEA authorities learn that a new substance has been manufactured and is subject to abuse. Added to that time lag is the period required for the administrative procedures to be completed. Drug traffickers can engage in activity until that time without violating the Controlled Substances Act.

The Federal Food, Drug, and Cosmetic Act, while generally a valuable tool in regulating the drug industry, does not satisfactorily address the problem of designer drugs. It makes certain activity engaged in by those distributing "new drugs" as defined in the Act unlawful. Under 21 U.S.C. §355(a) it is unlawful to introduce or to deliver for introduction into interstate commerce any new drug unless an approval of an application filed under the section is effective or an exemption from the normal approval requirements applies. A violation of this section (for a first offense) is punishable by imprisonment for not more than one year and a fine of not more than $1,000. 21 U.S.C. §§331(d) and 333(a). Thus, to the extent that certain "designer drug" activity involves a "new drug" as defined in 21 U.S.C. §321(p), it would violate the Federal Food, Drug, and Cosmetic Act unless the requirements of 21 U.S.C. §355 have been met. However, the Food and Drug Administration does not channel its regulatory efforts to control the distribution of illicit, addictive drugs of abuse like designer drugs. This makes sense, for FDA is not equipped to conduct the types of investigations of illicit drugs and other enforcement activities conducted by DEA and the FBI. Accordingly, FDA has not undertaken any enforcement activities involving designer drugs.

The proposal in S. 1437 in effect combines elements of the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act. It makes it a crime punishable by imprisonment for fifteen years and a fine of $250,000 under the Controlled Substances Act to manufacture with the intent to distribute, to possess with the intent to distribute, or to distribute a "designer drug" intended for human consumption without having complied with the provisions of the Federal Food, Drug, and Cosmetic Act.

Department attorneys, chemists, and regulators, as well as Department of Health and Human Services officials, considered several difficult issues in the development of S. 1437. The major hurdles that had to be overcome were: (1) the need to protect legitimate scientific research while effectively proscribing activity involving dangerous designer drugs; (2) depart-

ing from the basic approach of the Controlled Substances Act that relies on the scheduling of substances before activity involving them is prohibited; and (3) intermeshing two disparate statutory schemes, neither of which on its own is adequate to combat the problem. I shall address each of these considerations.

PROTECTION OF LEGITIMATE SCIENTIFIC RESEARCH

While a statute which effectively combats the designer drug problem must address a range of activities, including the manufacture of these substances, such a statute must also protect legitimate scientific research. That is, chemists should be free to conduct legitimate experimentation without fear of committing a serious federal felony. S. 1437 includes several features designed to protect legitimate scientific research and to assure that the proposed statute is not overbroad. First, it should be noted that the bill relates only to those substances which are substantially similar to controlled substances in Schedules I or II. This limitation was included because the most serious problems to date have involved substances which are similar to the drugs in one of these schedules. Next, the bill proscribes the manufacture with intent to distribute designer drugs, the possession with intent to distribute them, and the distribution of such substances only if they are intended for human consumption and only if the proscribed activity is knowing or intentional. Therefore, a laboratory chemist who experiments with molecules in an attempt to develop a new industrial chemical would not be affected by the proposed statute. One who experiments in the development of a drug for legitimate medical use -- specifically, for human consumption -- may have to consider the dictates of the bill but could avoid a violation. Most importantly, the bill provides an exemption mechanism tied to the new-drug approval process of the Federal Food, Drug, and Cosmetic Act. That is, activity regarding legitimate, new drugs is protected by the bill's exemption for manufacturing or distribution of a substance in conformance with the new-drug approval provision of the Federal Food, Drug, and Cosmetic Act, and early-stage research activity is protected by reference to the

exemption from the new-drug approval requirement for investigational use, 21 U.S.C. §355.

The bill in effect brings into operation the Federal Food, Drug, and Cosmetic Act's new-drug approval process or the exemption from its requirements at an early stage in the case of designer drugs in order for a legitimate researcher to avoid committing a violation of the proposed designer drug provision. Under the Federal Food, Drug, and Cosmetic Act the prohibited conduct does not occur until the stage of introduction or delivery for introduction of a new drug into interstate commerce in the absence of an approved new-drug application. 21 U.S.C. §355(a). However, under S. 1437 a violation would occur with respect to designer drugs in the absence of conformance with the new-drug approval process or an exemption from its requirements at the stage of manufacture or possession with intent to distribute, as well as at the distribution stage. It is intended that the new-drug approval or exemption process apply in the case of designer drugs at whatever stage is necessary to allow a legitimate researcher or manufacturer to avoid committing a violation of the proposed provision through compliance with this process.

Moreover, the bill explicitly states that for purposes of the designer drug provision the new-drug approval process of the Federal Food, Drug, and Cosmetic Act applies irrespective of whether the introduction or delivery for introduction of any new drug is into intrastate, interstate, or foreign commerce. The broad scope of the Controlled Substances Act (which requires no showing of an interstate commerce nexus) applies to the proposed exemption, as well as to the proposed offense. As a result, what serves as an exemption from the operation of the proposed provision -- conformance with the new-drug approval process of the Federal Food, Drug, and Cosmetic Act -- is as broad as the proscription itself.

A scientist experimenting in the development of a new drug for human consumption which meets the definition of a designer drug in S. 1437 could avoid violating the proposed criminal provision by operating initially pursuant to an exemption from the new-drug approval requirement for investigational use under

21 U.S.C §355(i). As a practical matter, we understand that under current law pharmaceutical companies routinely apply for an exemption at a very early stage in the development of a new product even though such an early exemption is not necessary to avoid a violation of the Federal Food, Drug, and Cosmetic Act. Thus, any adjustment of the application of the new-drug approval process for designer drugs brought about by S. 1437 should have little practical significance and is necessary to protect legitimate research while at the same time prohibiting the manufacture of designer drugs that are to be sold essentially as street drugs. I might add that any bill which failed to address the actual manufacture of designer drugs would be seriously deficient because it would have ignored one of the most serious aspects of the designer drug phenomenon.

DEPARTURE FROM THE APPROACH OF SCHEDULING SUBSTANCES

Another significant consideration in developing S. 1437 concerns the departure from the basic approach of the Controlled Substances Act -- that of prohibiting conduct regarding substances only if they are included in one of the schedules promulgated pursuant to the Act. Obviously, to the extent that activity is unlawful only if the substance in question is included in such a schedule, the public has an absolutely clear notion of what substances are the subject of the statute. In a sense, this aspect of the Controlled Substances Act represents an ideal situation and one duplicated by very few criminal statutes. However, when the problem is precisely that activity involving dangerous new drugs occurs prior to their inclusion in one of the schedules, this form of clarity provided by the scheduling of substances cannot be preserved. Thus, S. 1437, like most other criminal statutes, relies on definitions to describe the prohibited activity.

The term "designer drug" is defined by the bill to mean a substance other than a controlled substance (defined in 21 U.S.C. §802(6)) that has a chemical structure substantially similar to that of a controlled substance in Schedules I or II or that was specifically designed to produce an effect substantially similar

to that of a controlled substance in Schedules I or II. The definition also provides examples of chemical classes in which designer drugs are found.

The definition in S. 1437 provides a two-prong approach to the designer drug problem. A prosecution must be based on a substantial similarity in either chemical structure or effect between the substance in question and a Schedule I or II controlled substance. (If the effect prong is in issue, it must be shown that the substance was specifically designed to produce such an effect.) The prosecution must satisfy only one prong of this test, although evidence may be presented on both.

The bill incorporates these two separate standards because of the complex nature of the designer drug phenomenon and the need to provide flexibility in addressing a problem of which the boundaries are not yet known. In cases in which there is substantial similarity in chemical structure between the designer drug and a controlled substance, the evidence regarding the chemical similarity may be so difficult to grasp that evidence as to the drug's effect may aid in the proceeding by enabling the jury to choose a different route in determining whether a violation has occurred. Moreover, given the ingenuity of scientists and the technological advances we have witnessed in recent years, the designer drugs of the future may be quite different from the designer drugs of today. At present the designer drugs of greatest interest are substantially similar in chemical structure to Schedule I or II controlled substances. However, in the future substances may be developed which are not at all chemically similar to such controlled substances but which, nevertheless, are designed to and do in fact produce a substantially similar effect. These substances will be as useful to the illicit drug market as are substances which are chemically similar to controlled substances. Thus, in order to avoid incorporating a serious loophole, the bill includes the effect prong in the definition of designer drug. By the same token, there may be situations in which the chemical similarity between the substance in question and a controlled substance is so striking that evidence on this point will be very clear to the

finder of fact, and there will be no need to present evidence, which itself may be complex, on the effect of the substance.

To prove a violation under the bill, we would envision that the following types of evidence would be useful. Expert testimony by chemists who have performed laboratory analyses would be the basis for establishing the nature and degree of similarity when the chemical structure of the substance is in issue. Evidence regarding the similarity in effect would normally consist of expert testimony by scientists and physicians who have studied the substance in question and could be based as well on eyewitness accounts, admissions by the defendant to law enforcement officials or third parties regarding his or her intent, and information about transactions involving the substance.

The definition requires that there be a substantial degree of similarity in order for a substance to be considered a designer drug. Moreover, if the substance falls within the purview of the definition because of its effect, rather than its chemical structure, the substance must have been specifically designed to produce such an effect. Thus, for example, although caffeine may produce effects which resemble those produced by certain controlled substances, the similarity is not so significant as to bring caffeine within the purview of the definition of "designer drug"; nor would the intent accompanying its manufacture meet the relevant criteria of the "specifically designed to produce an effect" prong of the definition. For similar reasons, this proposal would not cover alcoholic beverages, tobacco products, over-the-counter medications or other legitimate consumer products. It should also be noted that while the definition of "designer drug" may include industrial chemicals, the definition must be read in relation to the substantive provision. A violation of the proposed provision would exist only if such a substance were intended for human consumption in connection with the proscribed activity. (The term "human consumption" is defined broadly to include application, injection, inhalation, or ingestion.) Moreover, as indicated earlier, the offense must be knowing or intentional.

The requirement that a designer drug be "substantially

similar" to a controlled substance describes the problem the bill seeks to overcome. That is, the bill's purpose is to prohibit persons who specifically set out to manufacture or to distribute drugs which are substantially similar to the most dangerous controlled substances from engaging in this activity. This similarity between designer drugs and controlled substances which the bill addresses is precisely the goal those who produce and distribute designer drugs wish to achieve. Thus, while the use of the term "substantially similar" may not typify other criminal statutes, we know of no better way in this context to define the conduct which should be proscribed than to identify the goals of those who engage in it. The usefulness of this approach is especially apparent when the term "substantially similar" is considered in light of the rest of the definition of the term designer drug. The similarity must relate to either the chemical structure of the substance in question or to the effect it was specifically designed to produce. The "substantially similar" standard indeed was developed in close consultation with DEA chemists who believe that it establishes an effective and workable test that can be supported by expert testimony. In fact, DEA has indicated that in most designer drug cases a substantial similarity in chemical structure, revealed through chemical analysis, will provide the basis for conviction.

We believe that S. 1437 would easily withstand constitutional attack on vagueness grounds despite the fact that it does not as clearly delineate those substances subject to its provisions as does the scheduling approach taken by the Controlled Substances Act. To avoid being deemed void for vagueness, a statute must "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972). In that case the Court upheld an ordinance prohibiting a person from willfully making a noise on grounds adjacent to a school building if the noise disturbs or "tends to disturb" the peace or order of a school session. The Court has also upheld as

sufficiently definite a statute which permitted the deportation of a person convicted more than once of any "crime involving moral turpitude" in the case of a person who had been convicted twice of conspiracy to defraud the United States of taxes on distilled spirits. Jordan v. De George, 341 U.S. 223 (1951). In considering the vagueness issue as though the deportation statute in question had been a criminal statute, the Court said: "difficulty in determining whether certain marginal offenses are within the meaning of the language under attack as vague does not automatically render a statute unconstitutional for indefiniteness." 341 U.S. at 231. See also United States v. Powell, 423 U.S. 87, 93-94 (1975).

It should also be noted that the constitutionality of a standard challenged as vague is closely tied to whether the standard incorporates a specific intent requirement. In Colautti v. Franklin, 439 U.S. 379, 394-395 (1979), the Court struck down as unconstitutionally vague an abortion statute which required a determination by the physician as to whether the fetus was viable or "may be viable" but which failed to include any standard of culpability for such determinations. On the other hand, S. 1437 clearly imposes several specific intent elements: the offense must be committed knowingly or intentionally; the manufacture or possession must be with intent to distribute the substance; the substance must be intended for human consumption; and if the substance is a designer drug by virtue of its effect, rather than its chemical structure, it must have been specifically designed to produce such an effect. The language in S. 1437 provides notice to persons who set out to manufacture or distribute substances which are substantially similar to controlled substances that such conduct shall be deemed unlawful.

The drugs recently scheduled pursuant to the emergency scheduling authority provided by the Comprehensive Crime Control Act would in our view qualify as designer drugs under the definition in S. 1437, were it not for the fact that they have now been included in one of the schedules of substances under the Controlled Substances Act, and are indicative of the types of substances which would satisfy the proposed definition. For

example, 3-methylfentanyl, an analog of the Schedule II narcotic analgesic, fentanyl, is an extremely potent morphine-like analgesic substance which, along with other fentanyl analogs, is sold on the street as "China White" or "synthetic heroin." This substance would meet the designer drug definition because of its chemical similarity to fentanyl (were it not for the emergency scheduling of 3-methylfentanyl, effective April 15, 1985, 50 Fed.Reg. 11690). There are many other fentanyl analogs which would also meet the proposed designer drug definition. Similarly, MDMA, known as "ecstasy," is an analog of the Schedule I hallucinogen MDA and the Schedule II stimulant methamphetamine and has become the subject of nationwide abuse. (Its scheduling became effective this past July 1, 50 Fed. Reg. 23118). If the designer drug proscription in S. 1437 had previously been law, the manufacture and sale of these substances would have been illegal prior to the emergency scheduling actions, and the many abuses of these dangerous drugs that led to their scheduling may have been prevented.

INTERMESHING TWO DISPARATE STATUTORY SCHEMES

The final major obstacle in drafting S. 1437 relates to the intertwining of two diverse statutes: the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act. While the major thrust of the former is to combat the illicit drug industry while placing necessary controls on legitimate industry to prevent the diversion of drugs into illicit channels, the basic approach of the latter is to protect the public in its use of drugs generally developed and sold for legitimate purposes. Thus, for example, the penalties under the Controlled Substances Act are generally higher than those under the Federal Food, Drug, and Cosmetic Act. In that the designer drug phenomenon is essentially a problem akin to illicit drug dealing (although without passage of S. 1437 the drugs are not illegal), it was decided that the proposed provision most appropriately belonged in the Controlled Substances Act. Since, however, the Federal Food, Drug, and Cosmetic Act focuses on legitimate industry operations, incorporation of aspects of that statute was neces-

sary to protect legitimate scientific research. Thus, the problems described earlier regarding the application of the new-drug approval process had to be solved in order to provide a realistic exemption through operation of the Federal Food, Drug, and Cosmetic Act. Finally, the choice of terms that would be appropriate to the operation of both statutes had to be considered in order to assure that the approach embodied in S. 1437 would be workable both from the standpoint of legitimate research and prosecutability.

By combining elements of both the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act, S. 1437 in our view would provide the needed legislation to combat a serious problem which is left unsolved by current law. Until effective legislation to combat the problem of designer drugs is enacted, chemists and drug dealers will continue to thwart the purpose of the federal drug laws and to market dangerous drugs with impunity.

Mr. Chairman, I would be pleased to respond to any questions you or members of the Committee may have. Thank you.

The CHAIRMAN. Mr. Trott, as you know, this legislation defines designer drug as being a substance substantially similar to a schedule I or II controlled substance in either its chemical structure or in its intended effect.

Could you or Mr. Haislip tell us what factors an expert witness would look to in determining whether the chemical structure of two substances is substantially similar, and could those factors be set out in the statute itself?

Mr. TROTT. Mr. Chairman, let me take a shot at that. First, I think that, as I said earlier, in consulting with the chemists they tell me that this is a discipline in which they engage quite frequently.

Senator Hawkins brought here a molecule of one of the drugs that we are talking about. Chemists, as a result of their testing by analyzing the molecules of a certain structure, will be able to indicate in court whether a substance is substantially similar or not in composition to a controlled substance.

We are convinced that that is a test that will be easily coped with in a court of law. The problem, if you try to get any more specific, is that you bring about the difficulty that we are now confronting. If you are more specific in describing the elements that you are after, you create holes into which the chemists can then go with their own varieties of exceptions to defeat the law.

We are absolutely convinced after talking with the experts that "substantially similar" is specific enough so that it will be able to be coped with both in investigations and prosecutions.

The CHAIRMAN. Mr. Haislip, this legislation provides that a legitimate chemist may conduct research involving designer drugs if he or she has obtained an investigational use exemption under the Federal Food, Drug and Cosmetic Act.

What are the mechanics of getting such an exemption, and how burdensome is the process?

Mr. HAISLIP. Mr. Chairman, this is a reasonably simple process; it has existed for many years. All of the companies and scientists involved in the development of drugs for these purposes are very familiar with it.

The burden of proof is not heavy. One must demonstrate that the basic animal and toxicity studies have been done with the compound before it is to be used with people. One must demonstrate one's scientific credentials and present the plan or scheme of research that is to be pursued.

Now, if that is done, then the Food and Drug Administration will provide this means, and this is not regarded as a difficult or heavy burden for legitimate scientists and research activity.

The CHAIRMAN. I do not believe you have testified yet. Would you care to go ahead now and testify?

Mr. HAISLIP. Thank you, Mr. Chairman, and I will be brief because so much outlining the problem has been said. I would like to first say that, of course, the Drug Enforcement Administration very much appreciates your attention and the attention of the other Senators who have spoken this morning in supporting us in dealing with this problem, as you have in all of the many difficult problems that we do have to face.

I would like to also submit for the record the statement of our Administrator, John Lawn, which was presented on July 25 before the Senate Subcommittee on Alcoholism and Drug Abuse. This statement details many of the matters that you will want to consider.

Let me just say this certainly represents one of the most unique and challenging problems that we have had to face in the law enforcement community. It has been an extremely rapidly developing problem. From month to month, we have seen significant changes, and I think the features in terms of the danger to the public and in terms of the technical difficulties have been quite well described here this morning and I will not attempt to repeat that, except as I may respond to questions you have in particular areas.

I would like to say that the Congress provided us with important new authority in the fall of last year as part of the President's anti-crime initiative which permits us to take emergency scheduling actions in this area.

This is an important authority that we never had before. In the past, it would take us 1, 2, and 3, and even more years to control a new drug found in the traffic. With this new authority, we can do it in record time, and we have used that authority given us by the Congress now to deal with four of the most deadly and threatening drug analogs or what have been popularly called the designer drugs.

I think that those legal actions we have taken have had enormous effect in dealing with the problem. However, as has been said correctly, this only deals with the problem after the fact, after the discovery, and perhaps after the distribution of large quantities of these drugs.

We are facing now a situation in California where there have been some significant arrests involving individuals who have manufactured perhaps millions of dosage units of the drugs that have been described to you this morning.

There may not be a violation that can be charged under the Controlled Substances Act because most of those that we have identified so far are drugs that we have not scheduled for control and, indeed, have not ever seen before.

So I think even though the legislation that the Congress enacted has been of enormous value and we have used it successfully and with good results already on four occasions, it shows that the problem has not been adequately addressed, and that is why we need the legislation that the Department has presented and that has been described by Mr. Trott to you.

I think that the bill as we have designed it is the best we can do. It provides a workable scheme. We believe that it will meet the test in court. We believe that the language we have chosen is sufficiently clear and instructive, particularly for the scientific community that deals with these compounds.

So we think that it represents a sensible next step in dealing with our problem. Mr. Chairman, that constitutes an overview of my statement. Thank you.

Mr. TROTT. Mr. Chairman, just briefly, I believe that there is no legitimate chemist in the United States or anywhere in the world who would be afraid of the reach of this statute for even 2 seconds.

As Mr. Haislip pointed out, what we have described is very particular, it is very clear, and it is easy to comport with if you are an honest person simply pursuing scientific research.

The CHAIRMAN. Thank you very much. Now, we have some other questions here, but I am going to let you answer those for the record, Mr. Trott and Mr. Haislip, if you will.

[Response to questions follow:]

U.S. Department of Justice

Criminal Division

Assistant Attorney General

Washington, D.C. 20530

SEP 30 1985

The Honorable Strom Thurmond
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Reference is made to the hearing of September 18, 1985, on designer drugs. I appreciated the opportunity to appear before the Committee, along with Gene Haislip of the Drug Enforcement Administration, and am pleased to respond to the questions set forth below. As you know, the first three questions on the list of questions you presented to me were posed and answered at the hearing. The following are answers to: (1) your remaining questions, (2) the questions directed to me which were submitted by Senator Denton, and (3) the questions of Senator Biden. Attached to this letter are DEA's responses to the questions directed to Mr. Haislip by Senator Denton and to a question posed by Senator Grassley.

1. "Is a lay jury equipped to make decisions as to the similarity of the chemical structures of different substances?"

A lay jury would be able to make decisions regarding the chemical structure of substances after considering expert testimony on this issue by chemists, who may resort to the use of models, diagrams, and other visual aids in presenting their opinions. Juries are confronted with complicated scientific evidence in many areas of the law, including medical malpractice suits and in criminal proceedings in which the identification of a particular substance as a controlled substance is in issue. We anticipate that juries will consider the technical aspects of designer drug prosecutions in the same manner as in other court proceedings.

2. "What factors would the courts examine in determining whether a given substance was specifically designed to produce an effect substantially similar to that of a Schedule I or II controlled substance? Is this a broad, generic test, or does it rely on the effects produced by each of the specific substances now on the schedules?"

We believe the courts would examine a variety of factors relative to the effects of a substance in issue. The effect prong of the definition will be most useful in situations in which the defendant makes statements to third parties or to law enforcement officials of his or her intent regarding the drug and the effects it has been designed to produce. Additionally, there may be eyewitness accounts regarding a drug's effects. However, courts would, in appropriate cases, also consider pharmacological factors, particularly those that relate to the drug's abuse potential, a criterion which must be considered in the scheduling of substances under Schedules I and II, 21 U.S.C. §812(b)(1) and (2), and one which must generally be considered under 21 U.S.C. §811(c)(1) by the Secretary of Health and Human Services in a scientific and medical evaluation conducted before scheduling

proceedings are initiated. In addition, the drug's "psychic or physiological dependence liability" -- a factor which must also be considered by the Secretary of Health and Human Services prior to a scheduling proceeding, 21 U.S.C. §811(c)(7) -- would generally be relevant in a designer drug case. Normally, the results of animal studies conducted on the substance in issue would provide information relevant to these considerations, particularly as to whether the substance is self-administering or addictive. The results of pharmacological testing would be presented at trial by an expert qualified in this area.

The similarity test under the definition in S. 1437 would not necessarily be a broad, generic test, although the above general factors would be relevant. Rather, we would expect the designer drug in question to be compared to a substance or a specific class of substances within Schedules I or II, such as the narcotics heroin and morphine in some cases or the hallucinogenic drugs LSD or mescaline in other cases.

3. "Mr. Trott, you say in your statement that alcohol, for example, would not fit within this 'intended effect' test, that it is not designed to produce an effect substantially similar to that of a substance controlled by the schedules. What is the basis for this statement, and do not Schedules I and II include other depressants?"

Although other Schedule I and II drugs may produce a depressant effect, alcohol produces a depressant effect to a different degree and by a different biochemical mechanism than the Schedule I or II depressants. Alcoholic beverages are not <u>designed</u> to produce the effects of these Schedule I or II depressants, despite the fact that alcohol abuse presents serious health hazards. The term "designed" connotes an objective, rather than a subjective, standard. It should be noted that the definition of "controlled substance" in the Controlled Substances Act, 21 U.S.C. §802(6), specifically excludes distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

4. "Our next witnesses, who represent the American Chemical Society, will suggest that the two definitions of a 'designer drug' be merged so that the prosecution would have to prove substantial similarity with regard <u>both</u> to chemical structure <u>and</u> to intended effect. Are you presently aware of any substance that you would label a designer drug that does not meet <u>both</u> these tests?"

We strongly recommend against changing the definition of designer drug to require a substantial similarity between the drug in issue and a Schedule I or II controlled substance in <u>both</u> the chemical structure and the effect the drug is designed to produce. A requirement to show a substantial similarity in both chemical structure and effect to a controlled substance would defeat the purpose of the bill. In many cases it would be extremely time-consuming to gather adequate pharmacological evidence regarding a drug's effect; it would not be unusual for such a process to take a year, depending upon the drug involved and the speed with which animal studies can be concluded. It is precisely because of the time required to develop such information and the dangers that many new drugs pose that the emergency scheduling provision was passed last year as part of the Comprehensive Crime Control Act of 1984. However, scheduling a substance pursuant to the emergency scheduling authority does not prevent abuses which precede the effective date of the emergency scheduling action.

We envision that the effect prong of the definition will be most useful in situations in which the defendant has made statements of his or her intent regarding the drug to law enforcement officials or to third parties. There may also be situations in which we have gathered information as to a drug's effect for other purposes, such as a scheduling proceeding, and could readily use it in a prosecution under the proposed provision. The flexibility provided by the current definition in S. 1437

would allow us to respond in the best manner to each new designer drug that is developed.

The chemical similarity prong of the definition independently provides an appropriate basis for prosecution. We believe that it reflects the intent of those who wish to evade the Controlled Substances Act by producing or distributing designer drugs. The designer drugs of which we are currently aware meet the chemical similarity standard. We believe that if they were subjected to pharmacological testing, it would be shown that they generally meet the effect standard as well, since in most cases of chemical similarity there is a great likelihood of similar effect. While there may be chemical analogs of Schedule I or II controlled substances which are not currently sold as street drugs and which do not produce effects which are substantially similar to those of Schedule I or II controlled substances, such substances are unlikely to be involved in a violation of the proposed provision. */ In order for a violation to occur, the substance must be intended for human consumption and must be knowingly or intentionally either manufactured or possessed with intent to distribute, or must be actually distributed. Moreover, the new-drug exemption provision in S. 1437 would be available for legitimate products which are chemical analogs of Schedule I or II controlled substances that are not otherwise excluded from the bill's coverage.

We have no objection in principle to stating in the legislative history that the purpose of the proposed Act is to prevent the manufacture and distribution of drugs designed to produce the effect of a Schedule I or II controlled substance. Such a statement of intent would help guide prosecutorial discretion in application of the statute. However, requiring specific proof of effect in each and every case beyond a reasonable doubt would, under the current state of scientific expertise, make a violation very difficult to prosecute successfully in court. The two-prong test which we advocate is the product of lengthy and well-considered study and analysis by experienced chemists, investigators, and prosecutors and represents the best mechanism possible to proscribe substances which are extremely dangerous to human life and to successfully prosecute and convict manufacturers and distributors of these substances.

5. "Would this change proposed by the chemists help in making the argument that the contemplated statute is not unduly vague?"

A requirement that a substantial similarity be shown between the drug in question and a controlled substance in both chemical similarity and effect would not in our opinion help support the argument that the contemplated statute is not unduly vague. As we understand the concerns expressed, it is the "substantial similarity" language that has caused some to question the proposal on vagueness grounds. Since the "substantial similarity" standard applies in the proposal to both the chemical structure and effect of the drug, requiring the prosecution to meet both tests would not make the proposal any more precise.

6. "How confident are you, Mr. Trott, that the vast majority of prosecutions under this Act can withstand vagueness attacks?"

We are confident that vagueness attacks will not prove successful. As indicated in my statement, the "substantially

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*/ An example of such a substance is naloxone, which is both an antagonist and analog of morphine. It is used to block the effects of morphine.

similar" standard in S. 1437 was developed in close consultation with DEA chemists who believe that it establishes an effective and workable test that can be supported by expert testimony. In each case the application of this test will present a question of fact to be decided on the basis of all the evidence on this issue. Obviously, some cases may present more difficult questions of fact than others. However, as the Supreme Court stated in Jordan v. De George, 341 U.S. 223, 231 (1951): "difficulty in determining whether certain marginal offenses are within the meaning of the language under attack as vague does not automatically render a statute unconstitutional for indefiniteness." The "substantially similar" standard expresses the goal which those who produce and distribute designer drugs wish to achieve and provides notice to the public of what activity is unlawful. We are confident that the federal courts will construe it in such a manner as to uphold it constitutionally, as they have in many other contexts when construing federal statutes.

7. "In discussing the vagueness issue, your statement emphasizes the various specific intent standards contained in the bill. Among other things, [the] prosecution must show that the defendant intended to distribute the drug, and that the drug was intended for human consumption. Would you see any harm in linking those two standards so that one element of the crime would be an intent to distribute for human consumption?"

We would oppose the linking of these two standards so that an element of the crime would be an intent to distribute for human consumption. Such a change in the provision may have the effect of precluding the application of the proposed statute to a chain of drug transactions or to the manufacturing or possession which may precede a chain of transactions. The courts may construe the proposed modification of the intent element to mean that a manufacturer must have an intent to distribute the substance to the ultimate user, rather than to others. Such a provision would provide an unwarranted defense to designer drug manufacturers who will claim that they do not intend to distribute the substance to persons who will consume it. Legitimate researchers can avoid violating the proposed provision by complying with the new-drug approval process or the exemption for investigational use under the Federal Food, Drug, and Cosmetic Act. This burden is not too great when the dangers of designer drugs are considered.

QUESTIONS SUBMITTED BY SENATOR DENTON

1. "These new designer drugs can have devastating effects on users, as you well know, due to their potency and toxicity. This potency also means that small amounts can yield astronomical profits. In light of the danger these drugs pose and the potential profits they promise, do you believe that the 15 year/$250,000 penalties provided in S. 1437 are adequate and will be effective?"

We believe that the penalties provided in S. 1437 are appropriate for the seriousness of the offense, that they will be effective, and that they comport with the penalty structure of the Controlled Substances Act. If a greater term of imprisonment were provided for designer drug violations, it would be a more serious offense to manufacture or distribute designer drugs than it would be to manufacture or distribute unspecified quantities of Schedule I or II controlled substances in violation of 21 U.S.C. §841(b)(1)(B).

2. "Do you have any evidence or indication that organized crime has become active in the manufacture or distribution of designer drugs?"

We have no indication at this time that organized crime has become involved in designer drug production or distribution. However, considering the huge profit potential in this area, we are monitoring the activities of traffickers very closely to be alert to possible organized crime involvement.

3. "You explained how the bill was carefully drafted to accommodate the needs of legitimate chemical researchers and drug manufacturers. Have you received any negative reaction from these groups regarding S. 1437?"

We have received a negative reaction from a representative of one drug manufacturer, who we understand has also communicated with a staff member of the Criminal Law Subcommittee.

QUESTIONS SUBMITTED BY SENATOR BIDEN

1. "Give an example as to how this new statute would work. The bill defines 'designer drug' as a substance that is 'substantially similar' in chemical structure or effect to a controlled substance on Schedules I or II. Can you give us an example of what would constitute a 'substantially similar' effect and what factors would you consider in arriving at that conclusion? It might also be helpful if you could give us an example as to how this new statute would work using the steps you would take from detection, arrest and prosecution."

An example of what would constitute a substantially similar effect would be a psychological or physiological dependence produced by a designer drug which is essentially equivalent to what is produced by the comparable class of Schedule I or II controlled substances. The factors that we would consider in arriving at a conclusion in this regard are discussed in our response to the second question considered above.

As an example of how this new statute would work, from detection and arrest to prosecution, we would most likely become aware of a new designer drug through the normal law enforcement procedures we use in investigating violations regarding scheduled controlled substances and would continue to use many of the procedures applicable to controlled substance cases. In fact, in the absence of the proposed legislation, DEA agents have conducted investigations of what they thought were scheduled substances only to find later that the investigation had to be dropped because the substance in question was a designer drug and not subject to the Controlled Substances Act. If the bill were enacted, these same types of investigations would continue with the result that the case could proceed.

DEA agents who learn about designer drugs and who obtain good lead information through informants would begin surveillance measures to detect the source of the drugs and their channels of distribution. (Of course, at the time the investigation is begun, the agents may not know whether the substance of concern is a scheduled substance or a designer drug as defined in S. 1437.) As with many controlled substance cases, DEA agents would attempt to make an undercover purchase of a designer drug, once they have sufficient information regarding it. To the extent that the available information actually leads to a clandestine laboratory, surveillance of the laboratory and the eventual use of search warrants would be in order. It would of course be essential to obtain the substance in question so that it could be tested at a DEA laboratory to determine if it met the designer drug definition. One or more arrests, indictments, and prosecutions would then ensue if a positive determination regarding the substance were made. In most cases we would envision that the chemical structure of the designer drug, rather than its effect, would be in issue, and a DEA expert would testify as to the pertinent matters if the case were to proceed to trial. In general, we believe that designer drug cases will closely resemble other Controlled Substances Act investigations and prosecutions, with the exception that there will be a greater degree of reliance on expert testimony.

2. "The term 'designer drug' is defined in this bill as a substance with a chemical structure or effect substantially similar to that of a controlled substance in Schedules I or II. Can you tell us why you have limited the 'designer drug' definition to references to Schedules I and II only? Is it possible

that exclusion of a Schedule III reference could create a loophole in designer drug enforcement in the future?"

The definition of designer drug was limited in this manner because the designer drugs of interest to date have been similar to drugs included in Schedules I and II. We believe that drugs which are designed to resemble Schedule I and II controlled substances are the most likely ones to be of interest to drug users because of their greater abuse potential and the more severe level of psychic or physiological dependence they produce. While new drugs may be developed which resemble controlled substances in the other schedules, we believe that this likelihood is not so great since analogs of some, such as benzodiazepines ("Valium" and "Librium"), would be very difficult to synthesize, and the potential for abuse in general is not so significant, that inclusion of other schedules in the bill would be warranted at this time.

3. "You have talked about how you believe this legislation will help you legally go after those producing designer drugs but I'm interested in what steps you plan to take from an operations and administrative standpoint. Congress can make new laws for you to use but we also need to know if you need personnel and equipment to enforce those laws. Have you assigned specialized personnel to work these cases and are these people adequately trained with sophisticated equipment to investigate and detect those producing these high tech narcotics?"

If S. 1437 is enacted, investigations will most likely fall within the work of DEA's "clandestine lab groups," which currently investigate clandestine laboratories to determine if they are manufacturing scheduled substances. Personnel assigned to these groups have specialized expertise in dealing with the problems which surround the investigation of clandestine laboratories. This type of expertise will be valuable in the investigation of designer drug cases since many of the investigative duties will be the same regardless of whether the substances produced by a clandestine laboratory are scheduled substances or non-scheduled designer drugs. If S. 1437 is enacted, we will provide additional training and coordination regarding the new provision to assure that it will be appropriately and fully enforced. DEA is presently equipped to analyze designer drugs. Whether additional investigative equipment will be necessary if S. 1437 is enacted would depend on the volume and location of cases.

4. "Do we have any joint programs with the state and local authorities for analysis of these drugs or joint investigations of possible designer drug producers? Will additional resources be necessary to law enforcement or prosecution at the Federal level when this new bill becomes law?"

DEA currently provides laboratory analysis to assist state and local authorities. In addition, DEA conducts joint investigations with state and local law enforcement officials in clandestine laboratory cases. Of course, without designer drug legislation, we are not able to prosecute designer drug manufacturers and traffickers unless they have also committed violations of current law.

We have been satisfied with the appropriations provided by Congress for drug enforcement in the last years and expect to devote a portion of these resources to designer drug investigations and prosecutions if S. 1437 is enacted. If it should become necessary to seek additional appropriations for designer drug cases, we would make this determination in the future and seek additional funding accordingly.

5. "What do you suggest be done in the area of prevention and education, since I understand DEA currently has a general drug prevention program underway? Are materials and information on designer drugs part of that program? (If yes, please provide these materials to the Committee.)"

We believe that a publicity campaign outlining the dangers of designer drugs and the serious side effects produced by some of these substances should be undertaken by a federal agency. DEA currently makes a videotape depicting the Parkinson-like effects of MPTP available to DEA field offices for their use in educating law enforcement officials and concerned groups. (This videotape was shown at the hearing of the Committee on September 18.) In addition, DEA currently provides information to school athletic coaches and a parents' organization, "Parents for a Drug-Free Youth," regarding the hazards of drugs generally and has plans underway to include information on designer drugs. Materials on designer drugs which will be used in these programs are in the preparation stage.

6. "Mr. Trott, in your statement you mention that DOJ expects that prosecutors will base their proof of a violation on expert evidence that establishes that a substance is substantially similar in chemical structure or effect to a controlled substance on Schedules I or II. However, one of your colleagues, John Lawn of DEA, has indicated that detection and analysis of designer drugs 'requires considerable time, expertise, and sophisticated equipment that is not available to all analytical labs'. Is it possible that prosecutors may be discouraged in prosecuting under this act due to the time and expense necessary in proving a violation?"

While the detection and analysis of designer drugs require a high level of expertise and sophisticated equipment, DEA laboratories are equipped to carry out this task, and we are confident that in the vast majority of cases they will be able to identify the substance in question. It should be pointed out that the identification of substances even as scheduled substances under the Controlled Substances Act is often a very complex task but not one which we believe has discouraged prosecutors from proceeding with an otherwise sound case. We believe that in appropriate cases the time and expense necessary to identify a substance as a designer drug will be treated as one of the many challenges that must be met in a criminal case but one which can be met successfully.

Sincerely,

Stephen S. Trott
Assistant Attorney General
Criminal Division

Enclosure

Questions from Senator Denton:

1. I understand that some of these drugs are so powerful that they can be absorbed through the skin or simply inhaled when open in the same room. What special problems does this present to law enforcement agents and what special resources or equipment will be required to deal with these drugs?

Although very little information is available regarding the health hazards from the involuntary exposure to fentanyl and meperidine analogs, there is some basis for concern in this area. It is generally acknowledged that inhalation of or cutaneous contact with MPTP, an MPPP contaminant, can produce a Parkinson-like syndrome in exposed individuals. Likewise, inhalation of relatively small amounts of fentanyl or its analogs may result in respiratory depression which in some cases could lead to death. The greatest hazard from exposure to these and other substances are in clandestine laboratories where higher concentrations and greater quantities of the drugs and chemicals occur. DEA has initiated a program to educate agents and chemists to the hazards of substances found in clandestine laboratories in general and those involved in the production of fentanyl and meperidine analogs specifically. The program will also establish procedures for providing more frequent and extensive medical examinations for those working clandestine laboratory cases and review and up-date the type of equipment (masks, gloves, suits, etc.) to be used when securing and working in clandestine laboratories. However, it is essential that more scientifically sound data regarding the hazards from incidental exposure to substances found in clandestine laboratories is generated. This data is necessary to insure that informed decisions are made regarding the appropriate precautions to be taken when exposure to hazardous substances is likely.

2. How many controlled substances analogs have you encountered in the drug market to date, and how many have been added to the schedules of controlled substances?

The production of analogs of controlled substances for the purpose of avoiding the laws governing abusable substances is not new. In the 1960's the synthesis and distribution of several analogs of mescaline (3,4-methylendioxy-ampehtamine (MDA), methoxy-methylenedioxyamphetamine (MMDA), 4-methyl-2,5-dimethoxyamphetamine (DOM, STP), trimethoxyamphetamine (TMA), para-methoxy-

amphetamine (PMA), 4-bromo-2,5-dimethoxyamphetamine (DOB), and 2,5-dimethoxy-amphetamine (DMA) were encountered in the illicit drug traffic. MDA, MMDA, DOM and TMA were controlled under the Drug Abuse Control Amendments (DACA, a predecessor to the Controlled Substances Act (CSA)) and PMA, DOB and DMA were controlled administratively under the CSA. In the 1970's several analogs of PCP and mecloqualone, a methaqualone analog, were controlled administratively under the CSA.

The current wave of analogs of the narcotic substances meperidine and fentanyl began in 1980. Since that time DEA laboratories have identified 11 analogs of fentanyl, many of them in 1985, and 2 analogs of meperidine. Alpha-methyl-fentanyl, the first fentanyl analog encountered, was controlled in Schedule I of the CSA effective September 22, 1981. DEA used its emergency scheduling authority for the first time when 3-methylfentanyl was temporarily placed into Schedule I effective April 25, 1985. Several other fentanyl analogs currently are being considered for emergency scheduling. The meperidine analogs, MPPP and PEPAP, were temporarily placed in Schedule I through the emergency scheduling provision effective August 12, 1985. MDMA, an analog of MDA and methamphetamine, was also controlled under the emergency provision of the CSA on July 1, 1985.

3. Have you had enough time to determine whether the addition of a particular designer drug to the controlled substance schedules will discourage its continued sale and use?

Prior to its control in Schedule I of the CSA on September 22, 1981, alpha-methylfentanyl was associated with more that 20 overdose deaths and identified in 29 evidence submissions to DEA laboratories. Since 1982 there have been no known deaths associated with or lab submissions of alpha-methyl-fentanyl. The control of 3-methylfentanyl in April 1985 enabled DEA to arrest distributors of this substance who led agents to the suspected chemist believed responsible for the synthesis of 3-methylfentanyl. When this chemist was apprehended and his laboratory seized in June 1985, it was determined that he was no longer making 3-methylfentanyl. At least 7 other fentanyl analogs, all noncontrolled, were found. From these two examples, it appears that placing an analog of a controlled substance under the CSA discourages its production, sale and use but that clandestine chemists will switch to other noncontrolled analogs.

4. If this legislation passes, do you expect to see the continued addition of these analogs to the controlled substances schedule as they are identified or will there no longer be a need to do so?

It is envisioned that S.1437 will complement the scheduling of substances under the CSA and not obviate the need for scheduling. S.1437 will be used in those cases where a controlled substances analog has been newly identified and DEA has not had the opportunity to schedule it under the CSA. These newly identified substances will be reviewed for emergency and traditional scheduling and in most cases will be controlled.

Following is DEA's response to a question posed by Senator Grassley:
Unlike some other designer drugs, I understand that MDMA (Ecstacy) has become a national problem. Can you comment on this?

MDMA, or 3,4-methylenedioxymethamphetamine, is an analog of methamphetamine (Schedule II of the Controlled Substances Act (CSA)) and MDA, 3,4-methylenedioxyamphetamine (Schedule I of the CSA). As such it is a controlled substance analog. Unlike the narcotic controlled substance analogs, those of fentanyl and meperidine, MDMA production, trafficking and abuse has been found in many sections of the country. Available information indicates that the highest availability and use of MDMA is in Texas. It is estimated that one distributor in a Texas city was handling over 30,000 dosage units per month. Other areas where MDMA has been encountered include the West Coast, southern states and the East Coast from New England to Florida. Clandestine laboratories have been found in Tennessee, Florida, California, Georgia and Massachusetts. Laboratory submissions from at least 21 states, Canada and Germany, have been identified as MDMA. Drug treatment program personnel in California, Texas, New England, Florida and Virginia have reported treating individuals who have used MDMA. Since the temporary control of MDMA in Schedule I on July 1, 1985, DEA has made at least 8 arrests of MDMA distributors and seized over 50,000 dosage units. Additionally, chemicals, equipment and a tablet press used to produce MDMA were seized in Texas enroute from California to Mexico.

STATEMENT OF JOHN C. LAWN, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE

Chairman Hawkins and Members of the Committee:

I appreciate this opportunity to appear before you to discuss the very serious problem of designer drugs and to specifically comment on the provisions of S. 1437.

The designer drug phenomenon is fast becoming a serious challenge to the United States efforts against drug trafficking and control. This new dimension to the clandestine laboratory problem is being spearheaded by sophisticated chemists who manipulate the molecular structure of powerful, controlled drugs to create new drugs not controlled under Federal or state statutes. The proliferation of these designer drugs requires that we review our existing authorities to control this new threat to the public safety.

BACKGROUND

By way of background, the term designer drugs refers to clandestinely produced substances which are chemically and pharmacologically similar to substances listed in the Controlled Substances Act (CSA) but which are not themselves controlled. These analogs or chemical variants of controlled substances are not subject to the provisions of the Controlled Substances Act unless or until they are controlled in one of the five schedules of the CSA. The aim of the clandestine chemists is to manufacture substances which produce the effects of controlled narcotics, stimulants, depressants or hallucinogens, but because they are slightly different chemicals they are not controlled under the CSA. The designer drug phenomenon represents an attempt by unscrupulous individuals to reap tremendous profits from the distribution of dangerous drugs at the expense of the public health and safety and without fear of prosecution.

The concept of producing analogs of controlled substances in an effort to circumvent the existing drug laws is not new. The clandestine production, distribution and use of a number of

hallucinogenic amphetamine analogs of mescaline such as MDA, MMDA, STP and TMA first appeared in the late 1960's. The enactment of the Controlled Substances Act in 1970 which provided for administrative scheduling of substances was, in part, a response to this phenomenon. Chemical variants of methaqualone, PCP and amphetamine surfaced later in the 1970's. All of these early designer drugs were subsequently placed under the Controlled Substances Act through the administrative scheduling mechanism. The novel aspect of the current wave of designer drugs is the production of very potent analogs of synthetic narcotics which have been substituted for heroin.

The designer drugs of current concern focus on chemical variations of the Schedule II synthetic narcotic analgesics, fentanyl (marketed as Sublimaze®) and meperidine (marketed as Demerol®). Fentanyl is a short-acting, highly potent narcotic which is used as a surgical anesthetic. In humans it is about 100 times more potent than morphine. Meperidine is a narcotic analgesic approximately 1/6 to 1/8 as potent as morphine in humans. There are numerous chemical variants of both of these drugs which produce effects similar to those of morphine and heroin. Additionally, analogs of the hallucinogenic amphetamines continue to surface, as evidenced by the recent surge in the use of MDMA, known on the street as "Ecstasy."

As the lead Federal agency responsible for curtailing drug trafficking, DEA has been closely monitoring the designer drug phenomenon since its inception. I will now describe the current status of the problem involving fentanyl, meperidine and hallucinogenic amphetamine analogs, DEA's efforts to combat the designer drug problem, my assessment of the impact of these efforts, and the need for further legislation.

THE DESIGNER DRUGS OF THE '80's

The alpha-methyl analog of fentanyl was the first of the narcotic designer drugs encountered in the illicit drug traffic. Although it was not specifically identified by the DEA Special

Testing and Research Laboratory until January 1981, alpha-methylfentanyl was associated with narcotic overdose deaths in California as early as December 1979. Alpha-methylfentanyl was sold on the street to heroin addicts as synthetic heroin or "China White." It was associated with over 20 overdose deaths in California between December 1979 and December 1981. One overdose death each in Oregon and Arizona was also attributed to alpha-methylfentanyl during this period. Effective September 22, 1981, DEA placed alpha-methylfentanyl into Schedule I of the CSA by its administrative process. This action apparently eliminated the production and distribution of alpha-methylfentanyl. Other fentanyl analogs, however, were produced almost immediately to take the place of alpha-methylfentanyl in the drug traffic.

Since 1981, DEA laboratories have identified seven other fentanyl analogs. Over 75 drug evidence samples submitted to DEA laboratories have contained fentanyl analogs. More than 65 of these samples have been analyzed since January 1984--24 since January 1985. Most of these analogs had been described in the scientific literature. Two of the analogs, however, could not be found in the scientific literature. Some, such as para-fluorofentanyl, were encountered only one time, while others, such as 3-methylfentanyl, have been identified in over 40 submissions to DEA laboratories.

The health risks attendant to the use of the various fentanyl analogs are greater than those associated with the use of traditional narcotics, such as heroin or morphine. The high potency of the fentanyl analogs creates a substantial risk of fatal overdose. Indeed, the various fentanyl analogs have been associated with more than 95 known overdose deaths since December 1979. There were at least 31 overdose deaths in 1984 and at least 26 thus far this year. A continuing increase in the availability and use of these substances since January 1984 is borne out by the increase in submissions of fentanyl analog samples to forensic laboratories and the greater number of fentanyl analog related deaths. With very few exceptions, these

reports have come from California. Moreover, in those cases not reported in California, the source of the fentanyl analog was identified as California.

Researchers at the University of California at Davis recently attempted to determine the incidence of fentanyl analog use by clients of several California methadone maintenance programs through the use of urine screening tests. Their results showed that approximately 10% (range 0-24%) of the clients tested had used fentanyl analogs either knowingly or unknowingly. The fentanyl analogs are extremely potent; only minute quantities are necessary to produce the desired effects. Further, the clandestine production of these substances yields a number of by-products and impurities. Detection and identification of fentanyl analogs as a class, or individually, in biological or powder samples requires considerable time, expertise and sophisticated equipment not available to all analytical laboratories. In light of the above, it is highly likely that the prevalence of fentanyl analogs is underreported and, therefore, a clear picture of the magnitude and scope of the fentanyl analog problem is difficult to measure.

All of the fentanyl analogs identified in the illicit traffic are potent narcotics with rapid onsets and relatively short durations of actions. They produce a spectrum of heroin-like effects including euphoria, addiction-sustaining liability and respiratory depression. In humans, these fentanyl analogs range in potency from about 10 to 250 times that of heroin. Consequently, whereas a 1.0 gram quantity of heroin would yield approximately 200 dosage units, the same quantity of 3-methylfentanyl would yield 50,000 dosage units. The scientific literature describes analogs of fentanyl even more potent than 3-methylfentanyl. Fortunately, there are no reports of these substances in the illicit drug traffic.

It is evident from the type of compounds produced and the methods of synthesis employed that the individuals who are

operating these clandestine laboratories have a substantial amount of education and training in chemistry. However, the impurities and by-products present in the samples analyzed indicate that these chemists do not practice quality control. We surmise that maximum profits appear to be more important than quality products. It is estimated that one kilogram of a fentanyl analog, which is equivalent to as many as 50 million dosage units, could be manufactured for under $2,000. The street value of this quantity of fentany analogs would be over one billion dollars. Obviously, the financial rewards of such an endeavor are enormous and enticing.

While the use of the fentanyl analogs carries a substantial risk of drug overdose, the use of MPPP, a meperidine analog, carries an additional health risk. The synthesis of MPPP, unless performed under carefully controlled conditions, results in the formation of a by-product known as MPTP, a neurotoxic substance which induces an irreversible syndrome in man resembling Parkinson's Disease.

The first reported episode of MPPP abuse came to light in 1976 when an individual who synthesized MPPP for his own use sought treatment for Parkinson-like symptoms after using MPPP. Parkinson's Disease is characterized by tremors, muscular rigidity, slowness of movement and speech, and a masklike, expressionless face. In 1982, DEA laboratories analyzed a number of MPPP samples taken from individuals who were hospitalized with this syndrome in California. These samples also contained MPTP. By the summer of 1983, neurologists at the Santa Clara Valley Medical Center reported that they were treating seven individuals for a Parkinsonian syndrome after their intravenous use of MPPP and MPTP. The Center for Disease Control, in a study conducted in California in January 1985, indicated that many more individuals may have been exposed to MPPP/MPTP since 1982. Although some of these individuals do not now exhibit these symptoms, it is possible that they may develop Parkinsonian syndrome as they age.

In 1985, DEA laboratories identified yet another meperidine analog, PEPAP, in the illicit drug traffic in California. It is also believed that chemists in a large-scale clandestine PCP laboratory seized by DEA in Brownsville, Texas in late 1984 were attempting to synthesize PEPAP. Only the PEPAP intermediate in the reaction sequence was found at this laboratory. Synthesis of PEPAP also results in the formation of a by-product similar in structure to MPTP which is known as PEPTP.

Both of the meperidine analogs identified by DEA laboratories (MPPP, PEPAP) produce morphine-like effects and differ mainly in their potency. MPPP is up to 30 times more potent than meperidine, while PEPAP is up to 70 times more potent than meperidine. MPPP is also lethal at significantly lower doses than meperidine.

Currently, the narcotic designer drug problem appears to be confined primarily to portions of California. Furthermore, drug abuse indicators suggest that it is a relatively small but significant and increasing problem there. Recent seizures of kilogram quantities of fentanyl analogs indicate an alarming increase in the potential availability of these substances. The potential spread of the synthetic narcotic analogs to other sections of the country is a real and frightening possibility and causes us concern. This possibility has become a reality in the case of one designer drug, MDMA, which has spread to many sections of the country.

MDMA, also known as Ecstasy, XTC or ADAM, is an analog of the Schedule I hallucinogen MDA and the Schedule II stimulant methamphetamine. Pharmacologically, MDMA produces effects similar to those of both MDA and methamphetamine. This designer drug is reminiscent of the so-called "alphabet soup psychedelics" of the 1960's. In addition to being distributed in the usual underground drug channels, MDMA was used by a small group of psychiatrists as an adjunct to psychotherapy, even though the FDA has not approved this use.

MDMA was first seen in the illicit drug traffic in 1972 and infrequently in the illicit drug traffic during the 1970's. The last few years has seen a spread and increase in the clandestine production, distribution and use of MDMA in many sections of the country. Open promotion of MDMA as a legal euphoriant surfaced in some areas. Pamphlets entitled "Ecstasy, Everything Looks Wonderful When You're Young and on Drugs," "Flight Instructions for a Friend Using XTC" and "How to Prepare for an Ecstasy Experience" appeared on college campuses. Street prices have ranged from $8 to $20 per dosage unit or $70 to $100 per gram. Over 70,000 dosage units of MDMA have been submitted to DEA laboratories since 1978. It has been reported that one individual in Dallas, Texas was distributing 30,000 dosage units of MDMA per month. Unlike the fentanyl and meperidine analogs which have been geographically limited, MDMA abuse has become a nationwide problem.

The use of MDMA has been associated with several medical emergencies and users have been seeking help at drug abuse treatment centers. Individuals have been taking multiple doses of MDMA and have reported severe anxiety reactions, paranoia, fear, sleep problems and depression. Moreover, recent studies conducted at the University of Chicago show that low doses of MDA destroy serotonergic nerves in the rat brain. Preliminary work with MDMA indicates that MDMA produces similar neurotoxicity. Serotonin plays a major role in pain perception, sleep, mood, aggression and sexual behavior. Experts believe that humans taking MDA or MDMA in reported dosages of 100-120 mg. could experience neurotoxic effects.

DEA RESPONSE

The Drug Enforcement Administration sees designer drugs as a serious threat to public safety. However, until and unless these substances are listed under the CSA, DEA can take no enforcement action against the individuals responsible for the production and distribution of these analogs. DEA has used its scheduling

authority to place several of the most dangerous and available designer drugs into Schedule I. In the case of alpha-methylfentanyl, DEA used the traditional scheduling provision of the CSA to place it into Schedule I effective September 22, 1981. Even if expedited, these types of scheduling actions under the normal administrative process of the CSA usually take several months.

Realizing the need for quicker administrative scheduling under the CSA for this dangerous group of drugs, the Administration submitted, as part of "The Comprehensive Crime Control Act of 1984," a provision for an emergency scheduling procedure. This new authority provides DEA with the most important tool currently available to combat the designer drug problem. Title V of this Act, the "Drug Enforcement Admendments," gave DEA the authority to temporarily place a substance into Schedule I of the CSA if the substance poses an imminent hazard to the public safety. The legislative history shows that Congress envisioned that the emergency scheduling provision would be used for designer drugs.

In the last four months, DEA has used this authority to expeditiously place into Schedule I of the CSA the most dangerous and highly abused designer drugs identified to date. DEA's first emergency scheduling action placed 3-methylfentanyl into Schedule I effective April 15, 1985. 3-methyfentanyl is the most potent of the fentanyl analogs identified thus far in the illicit traffic and was responsible for most of the designer drug overdose deaths in the San Francisco Bay Area in 1984 and 1985. Effective July 1, 1985, DEA placed MDMA into Schedule I of the CSA using the emergency scheduling provision. Escalating nationwide abuse of MDMA and research which indicated that the use of MDMA may result in neurotoxic effects led to the scheduling of "Ecstasy." I am pleased to report that in the week immediately following the scheduling of MDMA, DEA made several arrests of distributors of "Ecstasy" in Texas. Also, a laboratory equipped to synthesize and tablet MDMA was intercepted en route to Mexico from California.

Most recently, DEA has moved against MPPP, which has been linked to the development of Parkinson's Disease in its abusers, and a similar substance known as PEPAP. These substances will be in Schedule I effective August 12, 1985.

THE NEED FOR ADDITIONAL LEGISLATION

Despite the effective use of the emergency scheduling authority and DEA's subsequent enforcement actions, there remain individuals who continue to evade the law by producing and distributing new analogs faster than they can be controlled. Indeed, the fentanyl analogs seized from two suspected clandestine chemists in early June 1985 were uncontrolled analogs of fentanyl. It is only after these new analogs are identified and placed under emergency control that there can be any criminal liability. Although the emergency scheduling process has considerably shortened the time needed for scheduling actions, there still exists a time-lag between the production of these new designer drugs and their subsequent control under the CSA. Clearly, this loophole must be closed if we are to effectively combat the clandestine designer drug chemists and guard against hazards to the public safety. A key to effective action against designer drugs cannot be based on the individual substances themselves, since they can be readily modified and the number of these drugs may be infinite. Rather, we must turn our attention to the act of manufacturing and distributing these designer drugs.

The bill S. 1437 takes this type of approach. Specifically, the proposal would add a new section, 403A, to the Controlled Substances Act (21 U.S.C. §843A) to make it unlawful to manufacture with the intent to distribute, to possess with the intent to distribute, or to distribute a dangerous class of substances known as designer drugs intended for human consumption, unless such action is in conformance with Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §355, regarding new drug approval. The term designer drug is defined

for purposes of the proposed provision to mean a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedule I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedule I or II.

This proposal would impact on the designer drug phenomenon by making it illegal for clandestine chemists to manufacture and distribute these substances. Great care has been taken to assure that the proposed legislation would impact only on the undesirable activity and not on legitimate manufacture and research. This proposal, unlike one that would focus on the drugs themselves, does not set up a regulatory or administrative framework with which the legitimate industry and researchers would have to comply. It places no additional burdens on anyone legitimately involved with these types of substances. Legitimate activity regarding new drugs is protected by the exemption for manufacturing or distribution of a substance in conformance with the new drug approval provision of the Federal Food, Drug, and Cosmetic Act. Early-stage clinical research activity is protected by reference to the exemption from the new drug approval requirement for investigational use. Also, nonclinical research and industrial applications would not be affected since they are not "intended for human consumption."

The legislative definition drug provides additional protection for legitimate activity and a clear statement of the focus of the proposal. The term designer drug is defined to mean a substance other than a controlled substance (defined in 21 U.S.C. §802(6)) that has a chemical structure substantially similar to that of a controlled substance in Schedule I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedule I or II. The definition also provides exemples of chemical classes in which designer drugs are found. The definition requires that there be a <u>substantial</u> degree of similarity in order for a

substance to be considered a designer drug. Moreover, if the substance falls within the purview of the definition because of its effect, rather than its chemical structure, the substance must have been specifically designed to produce such an effect. Thus, for example, although caffeine may produce effects which resemble those produced by certain controlled substances, the similarity is not so significant as to bring caffeine within the purview of the definition of designer drug nor would its design meet the "effect" requirements of the definition. This proposal is not intended to cover alcoholic beverages, tobacco products, aspirin, or other legitimate consumer products and these, too, would not meet the definition.

The proposal also includes technical provisions which clarify the applicability of the new drug approval process of the Food, Drug, and Cosmetic Act and establish a definition for the term "human consumption." For the purposes of the proposed provision, the new drug approval process of the Food, Drug, and Cosmetic Act would apply irrespective of intent to introduce the substance into interstate commerce. Thus, the broad scope of the Controlled Substances Act (which requires no interstate commerce nexus) applies to the proposed exemption, as well as to the proposed offense, in contrast to the Federal Food, Drug, and Cosmetic Act's requirement to show delivery or introduction for delivery into interstate commerce. While this latter requirement may be interpreted broadly, it is not appropriate or necessary for the proposed criminal statute. The term "human consumption" is defined broadly to include application, injection, inhalation, or ingestion.

The approach taken by this bill provides for an effective and, most importantly, an immediate law enforcement response to the manufacture and distribution of designer drugs. No longer will individuals be able to circumvent the Controlled Substances Act through skillful manipulation of the chemical structure of

potent and dangerous drugs. This bill makes manufacturing with the intent to distribute or distributing a designer drug intended for human consumption a crime punishable by imprisonment for up to 15 years and a fine of up to $250,000. This is done without placing additional burdens on legitimate industry and without restricting legitimate research.

CONCLUSION

The designer drug problem is indicative of the increasing complexity and technical nature of the drug abuse and trafficking situation. DEA has responded to this problem using every tool available to it and has, to this point, managed to put forward an effective effort against the most serious of these designer drugs.

We have fully implemented the emergency scheduling provisions of the "Comprehensive Crime Control Act of 1984" and have taken action against the most dangerous and highly abused of these designer drugs. These scheduling actions combined with our continued enforcement efforts are impacting on the traffickers of these dangerous drugs.

However, the nature of this phenomenon is such that the traffickers can and are circumventing our efforts by creating new uncontrolled analogs of controlled drugs. Without additional legislation, we will continually be one step behind many of these drug traffickers. This is a situation which obviously is not to be tolerated when people are being killed and crippled by unscrupulous individuals who manufacture and distribute designer drugs.

I will like to thank you, Madame Chairman, for calling these hearings to bring even greater attention to this important problem. I will be pleased to respond to any questions you or Members of the Subcommittee may have.

Thank you.

Mr. TROTT. Thank you very much, Mr. Chairman. We appreciate the opportunity to appear before you.

The CHAIRMAN. We appreciate your presence here and your splendid testimony.

Our final panel consists of two representatives from the American Chemical Society, the Congressionally-charted organization of chemists and chemical engineers.

Dr. Ellis Fields, president of the Society, obtained a Ph.D. degree in physical organic chemistry from the University of Chicago. He holds the highest scientific post at Amoco Chemicals, where he has worked since 1950.

Dr. Patrick Hanna, vice chairman of the American Chemical Society's Medicinal Chemistry Division, is professor of Medicinal Chemistry and Pharmacology at the University of Minnesota Medical School.

Dr. Fields, we thank you; we thank the ACS for its concern with the problem at hand, and we will be very happy to hear from you two gentlemen. Dr. Fields, if you could present your testimony as briefly as you can, then we will put the entire statement in the record. I may have a few questions to propound to you.

You may proceed.

STATEMENT OF ELLIS K. FIELDS, PRESIDENT, AMERICAN CHEMICAL SOCIETY, AND PATRICK E. HANNA, PROFESSOR, MEDICINAL CHEMISTRY AND PHARMACOLOGY, UNIVERSITY OF MINNESOTA SCHOOL OF MEDICINE, AND VICE CHAIRMAN, MEDICINAL CHEMISTRY DIVISION, AMERICAN CHEMICAL SOCIETY

Dr. FIELDS. Thank you very much, Mr. Chairman. I shall be brief.

I am Ellis K. Fields, president of the American Chemical Society. The American Chemical Society is the world's largest scientific and educational organization dedicated to the discipline of chemical science. As set forth in its national charter, the Society is dedicated to the advancement of chemistry, the increase and diffusion of chemical knowledge, and the fostering of scientific interests and inquiry.

The American Chemical Society also promotes high standards of professional ethics among its members so that: one, they may communicate a true understanding of chemical science; two, avoid premature, false or exaggerated statements and claims; three, discourage enterprises or practices harmful to the public interest and welfare; and, four, share with other citizens a responsibility for the proper use of scientific discoveries.

The American Chemical Society, with its membership of over 135,000 individual chemists and chemical engineers, strongly believes in this code of ethics and expresses our abhorrence of the misuse of science and of chemical knowledge to manufacture and distribute so-called designer drugs.

The Society supports passage of S. 1437, the Designer Drug Enforcement Act of 1985, which would make it illegal knowingly to manufacture, possess or distribute designer drugs for human consumption.

The American Chemical Society realizes that chemical science is at the center of the designer drug problem and the Society stands ready to offer its scientific expertise to help find a solution.

I am pleased now to introduce to you Dr. Patrick E. Hanna, who is vice chairman of the American Chemical Society Division of Medicinal Chemistry. Dr. Hanna is testifying on behalf of the American Chemical Society and will present the Society's position on the proposed legislation.

The CHAIRMAN. Thank you very much. Dr. Hanna, would you care to proceed?

Dr. HANNA. Thank you, Mr. Chairman. My name, as Dr. Fields said, is Patrick E. Hanna. I am a professor of medicinal chemistry and pharmacology at the University of Minnesota.

As vice chairman of the ACS Medicinal Chemistry Division and as senior editor of the Journal of Medicinal Chemistry, it is my pleasure to present the Society's position on the proposed legislation, S. 1437, the Designer Drug Enforcement Act of 1985. I am testifying with the approval of the American Chemical Society's Board of Directors and I request that the Society's written statement, together with a copy of the September 9, 1985, Chemical and Engineering News article entitled "New Variety of Street Drugs Poses Growing Problem," by Rudy M. Baum, be entered into the hearing record.

The term "designer drug" refers to compounds that result from modifications in the precise molecular structure of specific compounds with proven pharmacological activity and that are manufactured and distributed as drugs of abuse.

Currently, their production is entirely legal because the traditional method of controlling drugs of abuse is to classify or schedule specific chemical compounds as illegal under the Controlled Substances Act according to their precise molecular structure.

Schedule I drugs have no recognized medical application. Schedule II drugs have legitimate medical use, but may also be abused and have an addictive potential. Each variation in molecular structure, regardless of how slight, results in a new compound, referred to as an analog of the original compound.

These analogs are not scheduled drugs. Therefore, they are not considered controlled substances, according to the law. This is the legal loophole that the Designer Drug Enforcement Act seeks to close.

Reference has been made several times this morning to the ease of manufacturing designer drugs, and it is indeed unfortunate that often it is not difficult or expensive to manufacture these drugs. The equipment cost is low. The equipment and the starting chemicals are readily available. There are recipes for synthesizing the compounds in the published scientific literature. The training and scientific knowledge of the producer does not have to be that of a highly trained scientist or technician, and oftentimes quantities produced from a single synthesis are sufficient to last a lifetime.

Let us consider fentanyl, which is a legal, potent narcotic drug that can take the place of heroin. The compound fentanyl is marketed under the trade name Sublimaze and is used as an anesthetic in almost 70 percent of all surgical procedures in the United States.

Fentanyl is about 100 times more potent than morphine. The euphoria or high associated with fentanyl appears to be similar to that associated with heroin. Fentanyl is a complex molecule and a

vast number of relatively minor modifications of its molecular structure will result in analogs that are potent narcotics, sometimes more potent than fentanyl itself.

Let us consider the analog 3-methyl fentanyl, a designer drug that is approximately 3,000 times more potent than morphine and that has a duration of action and a high that are indistinguishable from heroin.

This fentanyl analog is relatively difficult to synthesize, as it involves complex chemical reactions requiring more sophisticated technical expertise. However, the equipment required could be found in any introductory organic chemistry laboratory. Also, synthesizing 3-methyl fentanyl even once could produce a lifetime supply. Two hundred grams is equal to approximately 200 million doses.

The profit motivation is so great that less highly trained individuals have been attracted to the synthesis of fentanyl analogs for sale as drugs of abuse. An investment of several thousand dollars in lab equipment and chemicals used to produce just 1 kilogram of 3-methyl fentanyl would net an enormous profit on the street. The chances of producing impure, more dangerous compounds increase as less highly trained individuals attempt to make designer drugs. The fentanyl analogs, primarily 3-methyl fentanyl, have been responsible for more than 100 overdose deaths in California.

Another potent narcotic drug analog that has appeared on the street is 1-methyl-4-phenyl-4-propionoxy-piperidine, also known as MPPP. Unlike 3-methyl fentanyl, MPPP is a rather simple molecule to synthesize, in that less technical expertise is required.

However, the reaction sequence must be carried out under the proper conditions. If the reaction is carried out at too high a temperature or too low a ph, much of the product will contain an impurity. That impurity is 1-methyl-4-phenyl-1,2, 5,6-tetrahydropyridine, which is known as MPTP.

Working from a set of instructions found in a journal article to produce MPPP, a designer drug manufacturer produced a drug batch of MPPP containing a high concentration of MPTP. This mixture was sold as synthetic heroin in 1982 near San Jose, CA, and caused the first designer drug disaster. This so-called new heroin produced severe brain damage with symptoms similar to the end stages of Parkinson's disease in its users.

Emergency scheduling provisions have been used to classify both MPPP and 3-methyl fentanyl as schedule I drugs, making them illegal. However, emergency scheduling on a case-by-case basis is an inadequate method to deal with the emergence of new designer drugs.

The American Chemical Society believes that the Designer Drug Enforcement Act provides a solution. The proposed legislation amends the Controlled Substances Act by imposing criminal penalties for manufacturing, possessing, or distributing designer drugs for human consumption.

However, the legislation also contains specific language exempting substances manufactured or distributed in conformance with an approved new drug application or in conformance with an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug and Cosmetic Act, which applies to the

introduction of any new drug into intrastate, interstate or foreign commerce.

Although the American Chemical Society believes that this language protects legitimate research and development of new pharmaceuticals, the society recommends that the committee's written report, the legislative history of this proposal, contain specific language with examples illustrating that there is no intent to interfere with, and that there will be no negative impact on, legitimate pharmaceutical research.

There are many legitimate scientific reasons for a substance, which may fit the definition of a designer drug, to be synthesized in drug research solely for its chemical utility and not intended for human consumption.

The society believes that protection of this legitimate drug research is vitally important and would urge that the congressional intent not to interfere with this research be clearly stated in the legislative history.

Although additional protection for legitimate research and a statement of the focus for this legislation is contained in the definition of a designer drug as a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in schedules I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in schedules I or II, the American Chemical Society believes that legitimate research would be more adequately protected if the "or" in this definition were changed to "and."

This change of "or" to "and" would emphasize the designing of these substances to produce substantially similar biological effects to those of controlled substances. With these safeguards, the society believes that this legislation will not adversely affect anyone involved in legitimate drug research.

Designer drug manufacturers have violated the values of our profession by misusing their knowledge of chemical science. The society believes that the Designer Drug Enforcement Act offers the necessary and desirable legal solution to the problem of designer drugs, and we support its passage.

We, as chemists 'are proud of our profession and dedicated to guarding its high standards of conduct. We appreciate the opportunity to express our views and to offer our support for S. 1437. Thank you, Mr. Chairman.

The CHAIRMAN. Dr. Hanna, you have testified that the bill's language concerning substances manufactured or distributed in conformance with an exemption for investigational use under the Food, Drug and Cosmetic Act protects legitimate research.

Can you tell us how burdensome it is to obtain such an exemption?

Dr. HANNA. I have no direct personal experience with obtaining such an exemption. My colleagues in the pharmaceutical industry do this routinely. There is a fair amount of work involved, but it is certainly not unusual for it to be done. Certainly, the American Chemical Society would have no trouble getting that information for you if you would like us to provide it.

The CHAIRMAN. Dr. Hanna, you have also proposed an amendment merging the two "substantially similar" tests. Do you know

of any substance that meets one of these tests but not the other? What do you see as the practical effect of such an amendment?

Dr. HANNA. First of all, I believe that the amendment will make the definition of "designer drug" a more focused and more concise definition. If you look at the first half of the definition—a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance—there are, in clinical use, therapeutic agents which have structures that are very similar to the structures of controlled substances, but they have much different pharmacological effects, and these are useful drugs.

But according to this definition, those drugs would meet the definition of a designer drug. An example of this is the drug aloxone, which is, I think by most people's definition, substantially similar in structure to morphine and heroin, but aloxone is an antagonist of the actions of morphine and heroin and is used clinically to antagonize and block the effects of those agents.

The CHAIRMAN. Dr. Fields, can you give us some idea of what factors an expert chemist would consider in determining whether two substances are substantially similar in chemical structure? Is "substantially similar" a meaningful term in this context?

Dr. FIELDS. I think it covers most, if not all, the cases that would be considered. The chemist would prefer something more specific like "analogs," but even that would need some more definition. "Substantially similar" would describe the designer drugs under consideration, so I see no difficulty with that language.

The CHAIRMAN. Dr. Fields, how difficult would it be for amateur chemists to produce some of the kinds of drugs we are talking about?

Dr. FIELDS. An amateur chemist would have to have some training, but it would not require a high level of sophistication. I think that 2 to 4 years of college chemistry would be sufficient, especially if somebody were particularly bright.

My own personal view, and I am not voicing that of the American Chemical Society, is that this sort of thing could also be controlled—and I am speaking of law enforcement, where I am no expert—could be controlled through the legitimate houses that supply all sorts of intermediate chemicals, beginning chemicals, and equipment for handling chemical synthesis.

They would be under a burden not to supply anybody who is not part of the legitimate organization doing research and producing pharmaceuticals.

The CHAIRMAN. Thank you very much.

The National Association of Retail Druggists has a statement and I am going to ask that that go into the record, if there is no objection. It will be placed in the record.

[The following was received for the record:]

ACS 85-016

STATEMENT

of

DR. ELLIS K. FIELDS

and

DR. PATRICK E. HANNA

on behalf of the

AMERICAN CHEMICAL SOCIETY

Mr. Chairman and Members of the Committee:

I am Ellis K. Fields, President of the American Chemical Society. The American Chemical Society (ACS) is the world's largest scientific and educational organization dedicated to the discipline of chemical science. As set forth in its National Charter, the Society is dedicated to the advancement of chemistry, the increase and diffusion of chemical knowledge, and the fostering of scientific interests and inquiry. The ACS also promotes high standards of professional ethics among its members so that they may communicate a true understanding of chemical science; avoid premature, false, or exaggerated statements; discourage enterprises or practices harmful to the public interest and welfare; and share with other citizens a responsibility for the proper use of scientific discoveries.

The ACS, with its membership of over 135,000 individual chemists and chemical engineers, strongly believes in this code of ethics and expresses our abhorrance of the misuse of science and of chemical knowledge to manufacture and distribute "designer drugs." The Society supports passage of S.1437, the "Designer Drug Enforcement Act of 1985," which would make it illegal to knowingly manufacture, possess, or distribute designer drugs for human consumption. The American Chemical Society realizes that chemical science is at the center of the designer drug problem, and the Society stands ready to offer its scientific expertise to help find a solution.

I am pleased to introduce to you Dr. Patrick E. Hanna, who is Vice-Chairman of the ACS Medicinal Chemistry Division. Dr. Hanna is testifying on behalf of the ACS and will present the Society's position on the proposed legislation.

Mr. Chairman and Members of the Committee: My name is Patrick E. Hanna. I am a Professor of Medicinal Chemistry and Pharmacology at the University of Minnesota. As Vice-Chairman of the ACS Medicinal Chemistry Division and a Senior Editor of the Journal of Medicinal Chemistry, it is my pleasure to present the Society's position on the proposed legislation, S.1437, the "Designer Drug Enforcement Act of 1985." I am testifying with the approval of the American Chemical Society's Board of Directors, and I request that the Society's written statement, together with a copy of the September 9, 1985, Chemical & Engineering News article entitled, "New Variety of Street Drugs Poses Growing Problem," by Rudy M. Baum, be entered into the hearing record.

The term "designer drug" refers to compounds that result from modifications in the precise molecular structure of specific compounds with proven pharmacological activity and that are manufactured and distributed as drugs of abuse. Currently, their production is entirely legal because the traditional method of controlling drugs of abuse is to classify--or schedule--specific chemical compounds as illegal under the Controlled Substances Act according to their precise molecular structure. Schedule I drugs have no recognized medical application; Schedule II drugs have legitimate medical use, but may also be abused and have an addictive potential. Each variation in molecular structure, regardless of how slight, results in a new compound, referred to as an analog, of the original compound. These analogs are not scheduled drugs; therefore, they are not considered controlled substances according to the law. This is the legal loophole that the Designer Drug Enforcement Act seeks to close.

How easy is it to design and manufacture these drugs? Unfortunately, it's often not that difficult or expensive:

- Equipment cost is low.
- Equipment and starting chemicals are readily available.
- "Recipes" are in published scientific literature.
- Training and scientific knowledge of the producer need not be that of a highly trained scientist/technician.
- Quantities produced from a single synthesis are sufficient to last a lifetime.

First, let's look at a legal potent narcotic drug that can take the place of heroin. The compound fentanyl is marketed under the tradename Sublimaze and is used as an anaesthetic in almost 70% of all surgical procedures in the U.S. Fentanyl is about 100 times more potent than morphine. The euphoria or "high" associated with fentanyl appears to be similar to that associated with heroin. Fentanyl is a highly complex molecule, and a vast number of relatively minor modifications of its molecular structure will result in analogs that are potent narcotics, sometimes more potent than fentanyl itself.

Next, let's review the analog 3-methyl fentanyl, a designer drug that is approximately 3000 times more potent than morphine and that has a duration of action and "high" that are indistinquishable from heroin. This fentanyl analog is relatively difficult to synthesize as it involves complex chemical reactions requiring more sophisticated technical expertise. However, the equipment required could be found in any introductory organic chemistry laboratory. Also, synthesizing 3-methyl fentanyl even once could produce a lifetime supply; 200 grams is equal to 200 million doses.

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may fit the definition of a designer drug, to be synthesized in drug research--solely for its chemical utility and not intended for human consumption. The Society believes that protection of this legitimate drug research is vitally important and would urge that the Congressional intent not to interfere with this research be clearly stated in the legislative history.

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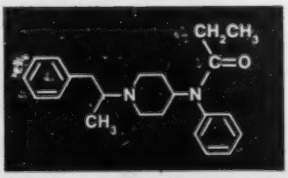
> ...a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedules I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedules I or II...,

the American Chemical Society believes that legitimate research would be more adequately protected if the "or" in this definition were changed to "and." This change of "or" to "and" would emphasize the designing of these substances to produce substantially similar biological effects to those of controlled substances. With these safeguards, the Society believes that this legislation will not adversely affect anyone involved in legitimate drug research.

Designer drug manufacturers have violated the values of our profession by misusing their knowledge of chemical science. The Society believes that the Designer Drug Enforcement Act offers a necessary and desirable legal solution to the problem of designer drugs, and we support its passage. We, as chemists, are proud of our profession and dedicated to guarding its high standards of conduct. We appreciate the opportunity to express our views and to offer our support for S.1437.

NEWS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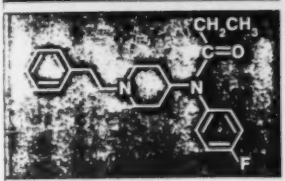
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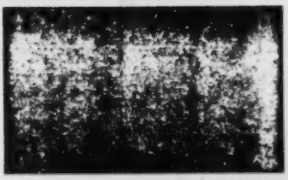

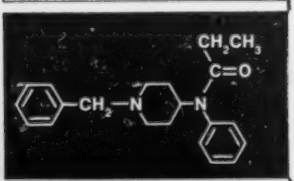
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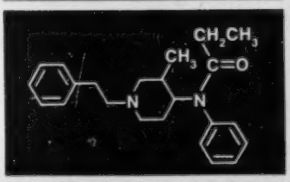
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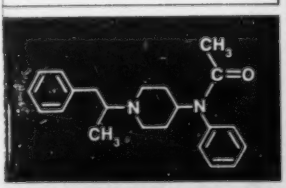
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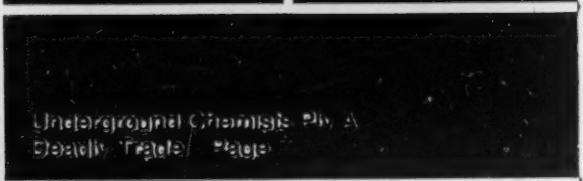
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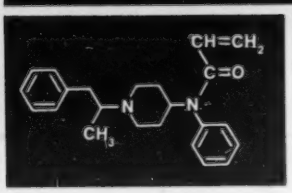
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New Variety of Street Drugs Poses Growing Problem

Designer drugs—analogs of compounds with proven pharmacological activity made by underground chemists—present novel challenges to law enforcement officials, legislators, and scientists

Rudy M. Baum, C&EN San Francisco

A breed of underground chemists, most of them in California, are playing a deadly cat-and-mouse game with law enforcement authorities. They are the manufacturers of what have become known as designer drugs. Their customers range from heroin addicts on the streets of Oakland, San Francisco, and Los Angeles to upscale young professionals in Marin County. Until recently, many of their products were perfectly legal. Until laws dealing with drugs of abuse are changed, it is likely that new products from their clandestine laboratories also will, for a time, be legal.

Designer drugs: It's a catchy sobriquet. It's also an imprecise one. Under its broad umbrella have been grouped compounds possessing enormously different pharmacological properties—and enormously different levels of danger to the people who consume them. One class of such drugs has been associated with more than 100 overdose deaths in California. An impurity in another designer drug has caused several cases of irreversible Parkinson's disease among the addicts who used it. Yet another has been condemned by some as a damaging hallucinogen and championed by others as an important new therapeutic agent.

The phenomenon of designer drugs presents law enforcement and drug treatment officials, legislators, and scientists with novel challenges. For example, how does one design a law to make illegal a compound that has not yet been synthesized? Or for another example, is it possible to design a simple, relatively inexpensive analytical procedure to detect a compound present in body fluids at 1 ng per mL? Ironically, the phenomenon also has opened up an exciting new avenue into the study of neurological disease, one that could never have been ethically pursued in the absence of several hundred young heroin addicts who poisoned themselves with a tainted designer drug.

Designer drugs are analogs of compounds with proven pharmacological activity manufactured by underground chemists for sale on the street. For instance, the compound fentanyl is a powerful narcotic marketed under the tradename Sublimaze by Janssen Pharma-

Doonesbury BY GARRY TRUDEAU

...AND I'D LIKE TO THANK DR. STAN FILBURN FOR ORGANIZING THE "MOONLIGHT WITH MOMA" THEME PARTY ON THE BEACH LAST NIGHT. WELL DONE, STAN!
OKAY, NOW, TODAY FROM 9:00 TO 9:15, DEAN HONEY WILL BE HOSTING A ROUNDTABLE ON THE ETHICS OF DRUG DESIGNING, AFTER WHICH WE'LL BREAK FOR LUNCH.
AT 2:30, THE MAIN EVENT. THOSE BRILLIANT TWINS FROM USC, DRS. ALBIE AND BUNNY GORP, WILL DEMONSTRATE HOW THEY BEAT THE FEDS WITH THEIR HOT, NEW, TOP 40 HYBRID — "INTENSITY"!
...AND WE JUST REMOVE THIS MOLECULE AND... VOILA!
LEGAL AS SEA SALT!
POP!

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ceutica of Belgium. Fentanyl is about 100 times as potent as morphine. It is very short-acting. Those properties have made it an extremely important drug in medicine—used as an anesthetic in, by one estimate, up to 70% of all surgical procedures in the U.S. Fentanyl is also just as addictive as heroin or morphine, and the "high" associated with it, though short-lived, appears to be very similar to that associated with heroin.

Fentanyl is not a simple molecule, and it turns out that a vast number of relatively minor modifications of its molecular structure result in compounds that also act as potent narcotics—in some cases, many times as potent as fentanyl itself. Tinker with a side chain here, add a halogen there, and the result is still probably a chemical that packs a powerful wallop, a chemical that can be sold on the street as heroin, and a chemical that might very well be as legal as sugar. It would still be legal because the traditional method of controlling drugs of abuse has been to classify specific chemical compounds as illegal. Until a compound is classified—a process known as scheduling—no laws apply to it.

The fentanyl analogs make up one of three classes of drugs that generally have been lumped together as designer drugs. Analogs of another, chemically distinct narcotic—meperidine—make up a second class. The third class contains a single member, 3,4-methylenedioxymethamphetamine (MDMA), which, for a number of reasons, probably should not be designated a designer drug.

The underground chemists who make these drugs—some of whom apparently are quite sophisticated, many others pure hacks—have borrowed a technique from medicinal chemistry. In the search for new pharmaceuticals, whether they be pain killers, antitumor drugs, or antihypertensive agents, medicinal chemists synthesize large numbers of analogs of known drugs and determine their properties. Sometimes the goal is greater potency, sometimes it is to find an antagonist, sometimes it is to find a drug with fewer negative side effects, and sometimes it is simply to beat a competitor's patent.

The motives and methods of the designer drug manufacturers, however, are different from those of the medicinal chemist. With a few intriguing exceptions, the quality control exercised by the illicit drug manufacturers is often lousy. Terms like "bucket chemists" and "biker labs" are used by drug enforcement officials and scientists to describe the majority of these producers and their facilities.

Another crucial difference between the underground entrepreneurs and their medicinal chemist counterparts is that the designer drug manufacturers are not fastidious about determining the pharmacology and toxicology of their products in test animals before marketing them. Food & Drug Administration approval is not a matter of concern to them. New compounds and concoctions of drugs and reaction contaminants are tested first in the humans they are sold to, which will lead, inevitably, to a "designer drug disaster," according to Robert J. Roberton, chief of the Division of Drug Programs of California's Department of Alcohol & Drug Programs. The first such disaster has already occurred. Roberton predicts that other such disasters will occur.

One motivation of underground analog chemists is to circumvent the laws governing illegal drugs—or controlled substances, as they are often called. Conviction for production or distribution of a drug that has been classified by the U.S. Drug Enforcement Administration as a Schedule I controlled substance—one with no medical uses and high abuse potential—carries a stiff fine and prison sentence. In a number of cases, analog chemists arrested by DEA or local law enforcement agents have simply been released because the compound being manufactured, although clearly a drug intended for sale, had not specifically been scheduled.

Although that factor has received much attention, it tends to overlook the fact that many drugs, from heroin to the notorious phencyclidine (PCP), have been controlled for many years and continue to be produced. And with legislation currently before Congress to control production and distribution of drug analogs in general and legislation before the California legislature to control fentanyl analogs specifically, the motivation of their technical legality may soon be obviated. Yet no one expects the analogs to disappear, because, like heroin and PCP, there is a market for them whether they are legal or not.

The biggest motivation is pure profit. According to Frank Sapienza, a chemist at DEA headquarters in Washington, D.C., in rough numbers a $2000 investment will yield about a kilogram of heroin worth about $1 million on the street. A similar $2000 investment in glassware and chemicals can be turned into a kilogram of 3-methyl fentanyl, currently the most common fentanyl analog being sold, worth about $1 billion (yes, billion!) on the street. Although producers of the fentanyl analog must worry about distribution, they do not have to contend with buying opium in foreign countries or smuggling their products into the U.S.

Analogs of controlled substances are not new. As Sapienza points out, "Analogs have been around at least since the 1960s. When we controlled LSD, mescaline, and some of the substituted amphetamines, underground chemists produced new analogs of them. When we controlled PCP, new analogs were formulated."

Most of the concern about designer drugs centers on the fentanyl and meperidine analogs. Even its strong detractors admit that MDMA is a different sort of drug altogether.

A number of features make the fentanyl and meperidine analogs different from previous analogs that have appeared on the street. One is that "for the first time, we are dealing with potent narcotic drugs that can take the place of heroin," Sapienza says. "The manufacturers do not have to go across the border to obtain their opium or refined morphine or heroin. They can make everything in a clandestine lab. To our knowledge, that has never been done before. It makes

Henderson (left): single chemist is responsible. Langston (center): synthetic heroin was behind disaster. Roberton: stepped-up education, prevention efforts

for a scary situation. The way things stand, we have no indication that organized crime is involved. We have no indication that it is a nationwide problem. However, in terms of the potential threat, there are half a million heroin addicts across the country primed to be supplied with these synthetic drugs."

Another feature is that, at least in the case of fentanyl analogs, the level of sophistication required to make even a sloppy batch and not kill oneself is greater than for past analogs. "Making these fentanyl compounds is not the same as making PCP or methamphetamine," Sapienza says. "I don't think that the average bucket chemist would be able to follow a set of instructions to make 3-methyl fentanyl."

The fentanyl and meperidine analogs tend to be linked together in discussions of designer drugs because both classes of compounds are narcotics and are intended for sale to heroin addicts, but they are quite distinct chemically. The evolution of the two as designer drugs also is different, as are the implications of their continued use on the street.

"Fentanyl has been in use medically in Europe since the late 1960s and in the U.S. since the early 1970s, and no one thought it had abuse potential because it is so short-acting. Addicts wouldn't use it if the high lasted only 30 minutes," says Gary L. Henderson, a pharmacologist and toxicologist at the University of California, Davis, who has been studying fentanyl and its analogs since 1972. However, Henderson points out, the fentanyls are unique in that the entire class of compounds is so potent, and analogs can be designed, as they have been by researchers at Janssen, to be either shorter acting or much longer acting than fentanyl itself.

Henderson's involvement with fentanyl began when he was asked to develop an analytical assay for the drug in body fluids for use in clinical monitoring. Because the compound is such a potent narcotic, it is present in very low concentrations in blood and urine of users, and development of such an assay is technically complex. The radioimmunoassay that Henderson and his coworkers fashioned has been improved to the point where it can now detect fentanyl or fentanyl analogs at concentrations as low as 1 ng per mL. Henderson's laboratory is the only one in California, and one of the few in the U.S., that can analyze for fentanyl analogs in body fluids.

Although fentanyl abuse by medical personnel is not uncommon, Henderson says, the first illicit use of the drug his laboratory was called on to investigate was in doping racehorses. "Racehorse underground chemists generally are years ahead of the chemists producing for street abuse," Henderson observes. The effects of narcotics are quite species specific, and in several species, including horses, they act as stimulants. "There is evidence that in ancient times opium extracts were used to stimulate horses. People were using methadone to dope racehorses before anyone in this country knew what methadone was," he says.

In 1981, Roberton contacted Henderson because fentanyl analogs had begun showing up in what were supposedly heroin samples seized by police. That contact has led to an ongoing contract between Henderson's lab and the Division of Drug Programs by which drug and body fluid samples from unexplained overdose deaths and from drug treatment centers can be sent to Henderson for analysis.

Over the past six years, several fentanyl analogs, as well as fentanyl itself, have shown up on the street, Henderson says. The analogs have appeared in a roughly sequential order with some overlap from one to the next. First came α-methyl fentanyl, then *p*-fluoro fentanyl, α-methyl acetyl fentanyl, and, in early 1984, 3-methyl fentanyl. At least two other analogs were found in samples but were probably synthetic byproducts, Henderson says. The α-methyl, *p*-fluoro, and

3-methyl analogs are now Schedule I controlled substances. To date, fentanyl analogs, primarily 3-methyl fentanyl, have been responsible for more than 100 overdose deaths in California.

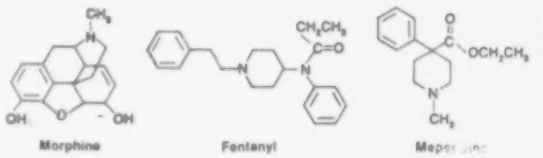
Henderson coined the term "designer drugs" specifically in reference to the fentanyl analogs he was analyzing. "I am probably going to be haunted by that until the day I die," he says. "It sounds like I am trivializing it, but I am not. We were getting samples that ranged from a pure white powder sold as China White to an off-white powder to a dark brown material that looked like Mexican Brown heroin. We got samples that were cut with heroin, and I wondered why someone would do that. It turns out that can help an addict get on a methadone program. The entire packaging and marketing concept to me was a designer phenomenon. Additionally, you could literally design the potency and duration of action into the molecule."

For a variety of reasons, Henderson believes that a single "world-class medicinal chemist" has been responsible for the various fentanyl analogs that have appeared. And the efforts of that anonymous chemist eerily paralleled those of reputable medicinal chemists seeking the ideal pharmaceutical. He or she found what was needed in 3-methyl fentanyl. It is extremely potent, about 3000 times more potent than morphine, and its duration of action and the high associated with it apparently are indistinguishable from heroin. "This gets misinterpreted, but 3-methyl fentanyl is actually a better drug than heroin," Henderson says. "It really is a designer drug. There is method to this madness. If someone said, 'Let's replace heroin,' this would be the way to do it."

Henderson bases his assessment that a single, highly sophisticated chemist has been responsible for all the fentanyl analogs that have appeared on several factors. One is that, apparently, all of the syntheses were carried out using starting materials and a highly efficient reaction scheme not in the published literature.

Another factor was the appear-

Morphine, fentanyl, and meperidine are useful narcotics . . .



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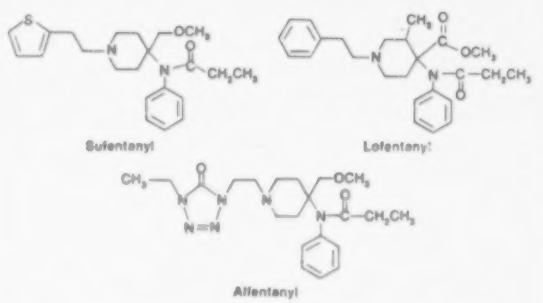
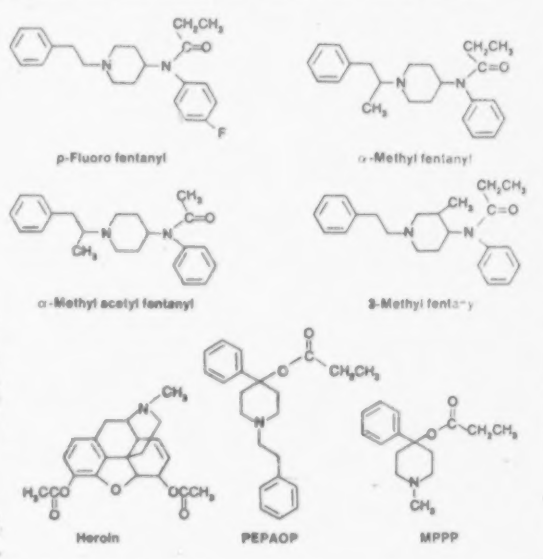


. . . while narcotic analogs are being sold on the street



ance of *p*-fluoro fentanyl. "That had not been described in the literature," Henderson says. "It is a straightforward thing to do, but unlike most underground chemists, he or she went to something that had never been published." A third factor is that "the quality control is really remarkable. These aren't garbage drugs. They are well made, with very few impurities, and the doses are uniform."

Finally, "the real kicker to me was the appearance of 3-methyl fentanyl," Henderson says. "It is hard to synthesize. There is a lot of steric hindrance at the 3-position. Plus, to make this, you stand a good chance of killing yourself. It is so potent in its pure form that you just can't work with it in a normal underground laboratory."

Overall, Henderson concludes, "the thinking behind this is an order of magnitude over your classic amphetamine or PCP chemist who works from a cookbook recipe." However, if the thinking behind the fentanyl analogs is world class, the facilities required to make it are not. "The equipment required is about what you would find in an introductory organic chemistry laboratory," Henderson says.

Henderson's speculation that a single chemist has been behind the fentanyl analogs that have appeared thus far may well be correct. The identity of that chemist likely will never be determined, because, Henderson believes, he or she no longer needs to synthesize product.

"That is one problem with the law enforcement end of this," Henderson says. "The police are oriented toward biker labs. They think they are going to be riding around and see a 50-gal drum of acetone sitting next to a garage. They go inside, and sure enough, some guy has boxes of 3-methyl fentanyl sitting around. That is not going to happen. You make 3-methyl fentanyl once and you have a lifetime supply; 200 g is 200 million doses."

Even if the scenario of a single chemist culprit is correct, it seems likely that other, less sophisticated chemists are being drawn to the synthesis of fentanyl analogs by the potential profits involved. Sapienza says that in June, DEA agents raided two independent clandestine laboratories in the Los Angeles area that were attempting to make some sort of fentanyl analog. Which analog, Sapienza says, is not yet clear. What is clear from the material that was seized is that the chemists involved were not of the caliber of the one who made the material Henderson has analyzed. "What we are seeing from both laboratories are complex mixtures of a number of active ingredients along with many by-product intermediates and impurities," Sapienza says.

The technical sophistication involved in analyzing for fentanyl analogs in blood and urine is causing headaches for drug treatment centers and parole and probation departments. Henderson is working to develop an assay for other laboratories, but he says, "I think it is a quantum jump in technology to make it routine." In addition to the low concentrations involved, different fentanyl analogs may require different immunoreagents.

Roberton outlines the kinds of problems the fentanyl analogs pose. "Say I am a parole officer. I have a man on parole who is required to give a urine sample on demand. He walks into my office one day and I can see that he is high as a kite. I say to him, 'You've been using,' and he responds, 'I haven't used in months.' So we get a urine sample, it goes into the lab, and it tests negative because he has not been using heroin, he has been using 3-methyl fentanyl. There is nothing I can do. It is a perfect drug for people on parole or on probation. People in drug treatment programs can use it, and it will not show up in the routine tests."

One company that does such routine testing is PharmChem Laboratories Inc., Menlo Park, Calif., which specializes in screening for illicit drugs, primarily in urine samples. The company analyzes about 50,000 samples per month from a variety of clients. Among PharmChem's largest clients, in terms of number of samples, are methadone treatment centers and parole and probation departments.

The type of analysis done depends on the client, says Brian Sedgwick, director of research and development of the company. For a typical sample from a drug treatment center, PharmChem carries out a relatively simple, two-plate, thin-layer-chromatography analysis, which can detect seven classes of drugs, including opiates, methadone, amphetamines, barbiturates, and cocaine. The cost of such an analysis is $3.00 to $4.00 per sample.

Samples from another client, the Los Angeles County probation department, undergo a three-test system. The sample is first screened by a two-plate TLC analysis. Samples testing positive are confirmed by an enzyme-linked immunoassay and then by gas chromatography. Only samples testing positive in all three procedures are reported as positive. Some industrial clients require gas chromatography/mass spectroscopy confirmation of positive samples, which adds about $45 to the cost of analysis, Sedgwick points out.

"The fentanyl series of compounds pose major analytical problems," Sedgwick says. For routine screening, the concentrations involved "are well below the range of TLC." That automatically means that immunoassay screening, which can be more expensive, will be required. Currently, an immunoreagent for fentanyl is not yet commercially available, Sedgwick says. And since GC/MS confirmation likely would be required for fentanyl analogs, the cost of analysis probably would be well beyond the budgets of most drug treatment centers and many parole and probation departments.

"If designer drugs do become a major part of the drug abuse scene, and if the trend is toward compounds with increasing potency, the implication for analytical laboratories such as PharmChem is that detection sensitivity will have to increase, and therefore our methodology will have to become more sophisticated, more precise, and possibly more expensive," Sedgwick says. Such trends would require a significant research and development effort.

The designer drugs that are analogs of meperidine

MDMA: A psychoactive drug with a schizophrenic reputation

Unlike the analogs of fentanyl and meperidine, the drug most commonly called MDMA has both its supporters and detractors.

To a number of psychiatrists scattered across the country, MDMA is a useful therapeutic tool. Those psychiatrists have been using MDMA quietly since the mid-1970s in counseling sessions as an adjunct to psychotherapy. They report that, when used under controlled conditions, MDMA has few negative side effects and can act to ease psychic trauma and break down barriers to communication.

To recreational users, whose numbers vary widely depending on the source of the estimate, MDMA is a pleasant way of getting in touch with oneself, of raising one's consciousness. To many such users, MDMA possesses the positive features of LSD without LSD's hallucinatory properties.

The National Institute on Drug Abuse (NIDA) maintains that MDMA is a "nationwide problem as well as a serious health threat." According to a NIDA publication, MDMA users experience problems similar to those associated with use of amphetamines and cocaine. The publication cites specifically "psychological difficulties, including confusion, depression, sleep problems, drug craving, severe anxiety, and paranoia—during and sometimes weeks after taking MDMA."

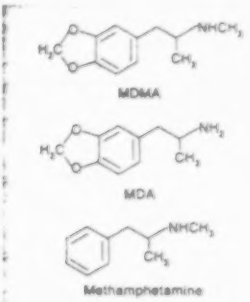
The Drug Enforcement Administration believes that MDMA is a drug with high abuse potential and no medical uses. As such, DEA recently invoked its emergency scheduling procedures to classify MDMA as a Schedule I controlled substance.

MDMA is an abbreviation derived from 3,4-methylenedioxymethamphetamine. Popular accounts of the designer drug phenomenon often cite the compound as an example of a designer drug. That classification has resulted largely because MDMA and designer drugs achieved notoriety simultaneously. MDMA's history and pharmacology, however, bear almost no resemblance to the analogs of fentanyl and meperidine.

MDMA was first synthesized and patented by E. Merck & Co., Germany, in 1914 as an appetite suppressant. The compound was never marketed, however, and the patent on it has long since expired. Until the DEA emergency scheduling, MDMA was not a controlled substance nor had it been approved by the Food & Drug Administration for medical use.

The compound goes by as many names as there are opinions regarding it. It has been referred to by at least half a dozen names in the scientific literature. Its currently accepted *Chemical Abstracts* designation is *N*,α-dimethyl-1,3-benzodioxole-5-ethanamine. On the street, it is sold as MDMA, MDM, Adam, Ecstasy, or XTC.

Chemically, MDMA is related both to methamphetamine and 3,4-methylenedioxyamphetamine (MDA). According to a number of research workers, however, it bears little pharmacological relationship to those drugs. "It stands out as unique in its constellation of properties," says one.



As is usually the case with psychoactive drugs, describing those properties in precise scientific language is difficult. Unlike MDA, MDMA appears to have almost no hallucinogenic properties. Nor is its effect primarily that of a stimulant such as methamphetamine. Instead, MDMA seems to break down barriers to communication between people, ease psychic trauma, and allow individuals access to repressed psychological information.

Because of those properties, some psychiatrists believe it is a useful drug in psychotherapy. George Greer, a psychiatrist in private practice in Santa Fe,

have followed a strikingly different path from that of the fentanyl analogs. Meperidine is a narcotic that was synthesized and patented in 1939 by Winthrop Laboratories and sold under the tradename Demerol.

The principal meperidine analog that has appeared on the street is 1-methyl-4-phenyl-4-propionoxy-piperidine (MPPP). It often is referred to as the "reverse ester" of meperidine. A synthesis and pharmacological evaluation of MPPP was first reported in 1947 by Albert Ziering and coworkers at Hoffmann-La Roche. The compound is about three times as potent as morphine and about 25 times as potent as meperidine. It was taken to clinical trials but never commercialized and never scheduled as a controlled substance.

Superficially, at least, MPPP is a simple molecule to synthesize. That, and its lack of a legal status, led to its discovery by one or more designer drug chemists. The reaction sequence, though simple, must be carried out under the proper conditions. If the reaction is carried out at too high a temperature or too low a pH, much of the product will be another compound altogether, 1-methyl-4-phenyl-1,2,5,6-tetrahydropyridine (MPTP).

Apparently working from a set of instructions derived from Ziering's journal article, an underground chemist managed to produce a drug batch that contained primarily MPTP. Sold on the street in 1982 in areas near San Jose, Calif., as "synthetic heroin," the MPPP/MPTP mixture caused the first designer drug disaster.

The key figure in unraveling that disaster was J. William Langston, chairman of the department of neurology at Santa Clara Valley Medical Center in San Jose. Langston was called in to examine a 42-year-old male heroin addict who was "literally frozen." "He couldn't move at all. He couldn't talk," Langston says. "There were some findings that suggested that he had

N.M., has published one of the few studies of such MDMA therapy. Greer administered MDMA to 29 subjects, 14 of whom were experiencing relatively minor psychological problems, such as dissatisfaction with themselves and minor depression. Although admitting that the study lacked rigorous scientific controls, Greer found that all 29 subjects reported some benefit from MDMA during the session.

Greer concluded that "the single best use of MDMA is to facilitate more direct communication between people involved in a significant emotional relationship. Not only is communication enhanced during the session, but afterward as well. Once a therapeutically motivated person has experienced the lack of true risk involved in direct and open communication, it can be practiced without the assistance of MDMA." Greer also observed that "MDMA's use as an adjunct to insight-oriented psychotherapy was specifically recommended by six subjects. Many felt that MDMA enhanced self-understanding and was useful in their personal and spiritual growth."

The psychiatrists who have used MDMA in therapy also believe that it has relatively low abuse potential because its beneficial or pleasant effects diminish rapidly with regular use.

By contrast, DEA's Frank Sapienza says that MDMA's abuse potential has been demonstrated by the simple fact that a lot of the drug is being synthesized, sold by dealers on the street, and used by recreational drug users. Based on that evidence and the fact that MDMA is chemically similar to other drugs of abuse, DEA proposed in July 1984 that MDMA be classified as a Schedule I controlled substance. The Schedule I classification was proposed because the Food & Drug Administration had never approved MDMA for medical use. "That is the definition we use," Sapienza says.

DEA was surprised when several psychiatrists and psychologists objected to the proposed scheduling. "We didn't know that it was being used in therapy sessions," Sapienza says.

In hearings on the scheduling, psychiatrists who have used MDMA in therapy argued that the drug should certainly be controlled, but that it should be classified as a Schedule III controlled substance, which is defined as one with moderate abuse potential and accepted medical uses. DEA's emergency scheduling action, coming in the midst of the permanent scheduling procedure, caught those physicians off guard.

Sapienza defends DEA's action on the grounds that research conducted at the University of Chicago demonstrated that MDA is selectively neurotoxic to serotonergic neurons in the brain. Although MDMA's mechanism of action remains unknown, research has shown that its action involves serotonergic neurons. By extrapolation, MDMA also might be neurotoxic to such neurons. DEA's emergency scheduling was based on that possible neurotoxicity and the increasing availability of the drug on the street.

"I think the different views of MDMA are compatible," Sapienza says. In terms of MDMA's abuse potential, he points out that the law does not equate abuse with harmful side effects. It equates abuse with how many people want to use a drug. And there appear to be a significant number of people who want to use MDMA. "They might not call that abuse," he says. "They might call it recreational use." However, the law does not differentiate between the two.

The same sort of dichotomy applies to what is meant by medically accepted uses. The law clearly states that a drug "must go through accepted procedures to prove that it is safe, that it can be produced in pure form, and that it treats some condition," Sapienza says. "MDMA may be able to fit into that category, but the studies have not been done to show that. Therefore, we have to say that it has no accepted medical use, and it has to go into Schedule I."

Such a classification, however, creates a catch-22 situation for the proponents of MDMA as a useful therapeutic drug. The laws applying to Schedule I controlled substances make it quite difficult to obtain approval to conduct clinical trials of a drug. Because it is impossible to obtain patent protection on MDMA, it is unlikely that a pharmaceutical firm will undertake the costly effort to obtain FDA approval for its use.

suffered neurological damage, but I had never seen anything like it before."

Langston and his colleagues found out that the patient's girlfriend, also a heroin addict, was in the same condition. She was admitted to the medical center. Although Langston was convinced that their condition was caused by some environmental source, he was not sure enough that it was the heroin to issue a public alarm. Then through what Langston calls a "remarkable series of coincidences," he learned of two similar cases in Santa Cruz, a town about 30 miles from San Jose on the California coast. Two brothers had used a synthetic heroin and both began to freeze up. They continued to use the drug until both were unable to move. Both probably would have starved had their mother not stopped by their apartment to check on them.

The link to the synthetic heroin had been established in Langston's mind, and he put out a public warning. The publicity surrounding the announcement brought to light three more cases and samples of the synthetic heroin. Ian Irwin, a chemist working with Langston, analyzed the samples by GC/MS, but found no matches against a library of 40,000 mass spectra.

The publicity resulted in yet another clue. Halle Weingarten, a toxicologist with the Santa Clara County Crime Laboratory, called Langston to tell him that she recalled reading about a student who had synthesized his own narcotics and been stricken with symptoms resembling Parkinson's disease. The case had been described by Glenn C. Davis, then an associate professor of psychiatry at the University of Tennessee's Center for the Health Sciences, and several coworkers in a 1979 issue of *Psychiatry Research*. After reading the article, Langston and Irwin concluded

that MPTP had been responsible for the student's condition. They then verified that the major constituent of the synthetic heroin samples sold in the San Jose area was, in fact, MPTP.

"That set off a real explosion of activity," Langston says. Once convinced that the condition of his patients was irreversible and strikingly similar to classic Parkinson's disease, Langston put them on L-dopa therapy. Parkinson's disease is caused by the death of dopaminergic neurons in an area of the brain called the substantia nigra. Dopamine is a neurotransmitter produced by the neurons of the substantia nigra, as well as by neurons in many other areas of the brain, and supplied to neurons of the striatum. It is necessary for normal muscle control. Dopamine cannot be administered orally, however, whereas L-dopa can. In patients with Parkinson's disease, L-dopa is converted by the remaining cells of the substantia nigra to dopamine. The response of his patients to L-dopa, Langston says, was dramatic.

However, although L-dopa therapy is a boon to Parkinson's disease patients, and probably proved life-saving for three of Langston's patients, disabling side effects, including hallucinations and exaggerated movements known as dyskinesias, are associated with it. These side effects appeared rapidly in Langston's patients, and in three of them maintaining an effective dosage has now become very difficult.

From a scientific point of view, the discovery that MPTP selectively destroyed neurons in the substantia nigra set off a major burst of activity in the study of Parkinson's disease, a field that had been relatively quiescent since the advent of L-dopa therapy almost two decades ago. Through the efforts of Langston and his coworkers and a number of independent researchers, many pieces of data fell into place over the following three years.

The authors of the 1979 *Psychiatry Research* paper had never identified the compound responsible for their patient's condition because they had focused on MPPP, not MPTP, Langston says. Those researchers studied the compounds in rats and, in doing so, made a double mistake. Rats respond to narcotics in a way that no other species does: They become catatonic. Rats also appear to be very resistant to MPTP-induced neuronal damage.

"What is interesting about that," Langston says, "is that a huge amount of experimental data in medicine is generated in rats. This is a stunning example in which rats do not predict the primate at all. If you did MPTP toxicity screening in rats, you would miss this completely."

Researchers then demonstrated that MPTP was selectively toxic to substantia nigra neurons in rhesus monkeys, and Langston and coworkers found that it had the same effect in squirrel monkeys. When the animals that had been treated with MPTP were sacrificed, the damage to substantia nigra neurons appeared identical to that observed in the brains of deceased Parkinson's disease patients. MPTP had provided an animal model of Parkinson's disease, something that researchers had never before possessed.

"To the best of my knowledge, MPTP is the most selective neurotoxin ever discovered," Langston says. "These discoveries have set off a real scientific race to find out how it acts. There are really three major questions. One is: Why is MPTP so incredibly selective and how does it destroy just one type of dopaminergic cell in the brain? The second is: What is the cause of the species selectivity? Primates are much more sensitive than rodents. The third question is: Will understanding the mechanism of action by which MPTP causes cell death help us to understand why those same cells die in Parkinson's disease? There is a great deal of hope that that will be the case. It could actually unravel Parkinson's disease. That is a big one in medicine."

What has been discovered is that MPTP is rapidly converted somewhere in the brain to the 1-methyl-4-phenylpyridinium ion (MPP^+). This conversion is catalyzed by the enzyme monoamine oxidase. Langston, Irwin, and coworkers have accumulated evidence that this conversion is necessary for MPTP to exert its toxic effects. They have shown that 1-methyl-4-phenylpiperidine, a compound lacking the double bond in the dehydropyridine ring of MPTP, cannot be converted to MPP^+ by monoamine oxidase and does not exhibit the neurotoxicity of MPTP. Another finding dovetailing with this is that monoamine oxidase inhibitors block the neurotoxic effect of MPTP.

Another important piece of evidence is that MPP^+, but not MPTP, is actively taken up by the dopamine uptake system at a rate similar to dopamine itself. "What probably happens is that some extraneuronal component, either neuronal support cells or cells somewhere else in the brain, converts MPTP to MPP^+, and then the nigral neurons take up the MPP^+," Langston says. Why the dopaminergic neurons of the substantia nigra are destroyed by the MPP^+ whereas other dopaminergic neurons seem not to be affected by it remains a mystery.

Is MPTP the cause of classical Parkinson's disease? That, too, remains an open question. Langston, however, has become convinced that, if not MPTP, then some other environmental factor is responsible for a large percentage of the cases of the disease. He and Donald B. Calne, a neurologist at the University of British Columbia, Vancouver, have published a hypothesis to that effect.

Langston explains that studies of twins have pretty much ruled out a hereditary explanation for the disease. It has been known that 5 to 8% of nigral neurons die naturally with each decade of life. However, 80% of such neurons must die before the first symptoms of Parkinson's disease appear. That means that most people never exhaust their reserve of such neurons during their lifetimes.

Langston and Calne suggest that most cases of Parkinson's disease result from an environmental insult such as exposure to MPTP that causes the death of some fraction of the nigral neurons during midlife. If that insult destroyed, say, 50% of the nigral neurons, there would be no symptoms. However, the natural process of nigral cell death would move that person

below the 20% threshold for such symptoms much earlier in life than would normally occur.

The MPTP-contaminated synthetic heroin is going to provide a crucial test for that hypothesis over the next decade, Langston points out. In cooperation with the Centers for Disease Control, Langston has identified more than 400 other people who probably used the tainted synthetic heroin. In a sense, they have volunteered for a grim epidemiological study. If the hypothesis is correct, many of those people will develop symptoms of Parkinsonism in the coming years.

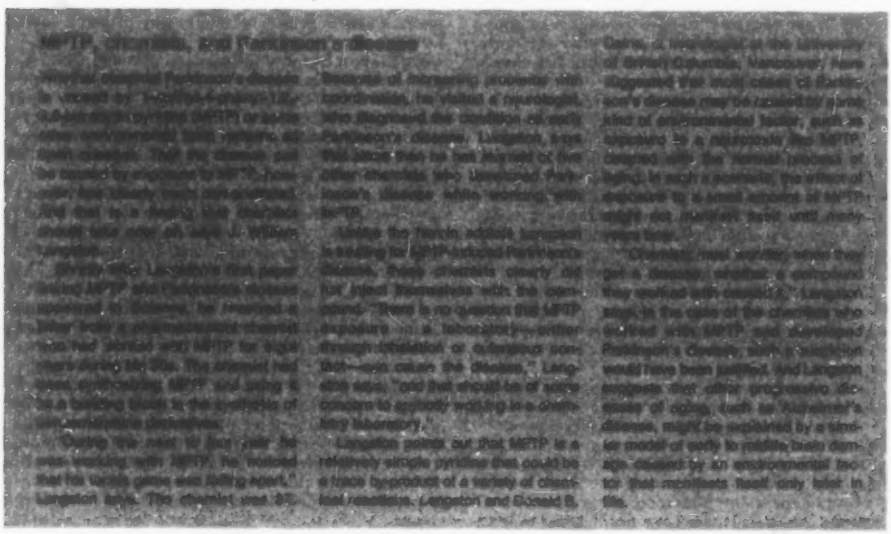
Another patient of Langston's developed symptoms that strongly resemble Huntington's chorea within an hour of using a synthetic heroin. Huntington's chorea is an inheritable disease involving the death of neurons in the basal ganglia, a region of the brain that connects with the substantia nigra. The patient was referred to Langston as a possible MPTP victim, but Huntington's chorea, Langston says, involves excessive uncontrollable movement, almost the opposite of Parkinson's disease. Langston was ready to dismiss the patient when he learned that the patient apparently had purchased his synthetic heroin from the same drug dealer that had sold the MPPP/MPTP concoction to the patients who developed Parkinson's disease.

Another meperidine analog, 1-(2-phenylethyl)-4-phenylacetoxypiperidine (PEPAOP), was identified in a sample of synthetic heroin in 1984, Langston says. Improper synthesis of PEPAOP can result in production of an MPTP analog, 1-(2-phenylethyl)-4-phenyl-1,2,3,6-tetrahydropyridine (PEPTP).

"We have been predicting a 'drug x' for about six months," Langston says, based on the patient with symptoms resembling Huntington's chorea and certain other symptoms that have been showing up in patients who use narcotics. "The question is: Could PEPAOP or PEPTP be drug x?" Langston asks. He has initiated studies of the neurotoxicity of the compounds in an attempt to answer that question.

Designer drugs have proven to be a source of enormous frustration for drug enforcement authorities. Until 1984, scheduling a compound was a procedure that could take up to several years. The Comprehensive Crime Control Act of 1984 gave the Attorney General emergency scheduling authority, which bypasses hearings involved in permanent scheduling. Under the law, a drug can be designated as a controlled substance within 30 days of a determination that it represents a hazard to public safety. The emergency scheduling remains in effect for one year. Emergency scheduling provisions have been used to classify MPPP, PEPAOP, and 3-methyl fentanyl as Schedule I drugs.

The Justice Department and many others, however, believe that emergency scheduling is inadequate to deal with the designer drug phenomenon. Legislation supported by the Justice Department and DEA was introduced in the Senate in July to control the analogs, even if they do not yet exist, of controlled substances. Titled the "Designer Drug" Enforcement Act, the legislation imposes penalties for manufacturing, possessing, or distributing a designer drug for human consumption. The act exempts substances manufactured or distributed in conformance with an approved new drug application or an exemption for investiga-



tional use so as not to interfere with legitimate research and development of new pharmaceuticals.

The act defines a designer drug as "a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedules I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedules I or II."

The bill is now before the Judiciary Committee. No hearings on it have yet been scheduled.

Response to the bill has been cautious, and many involved in the effort to control designer drugs refuse to comment on it beyond saying that it probably will emerge from hearings in somewhat different form. Many pharmaceutical manufacturers have not yet taken a position on it, although there appears to be some consensus that because the intent of the legislation is not to interfere with legitimate research, it will not pose a problem for drug companies. A spokesman for the Pharmaceutical Manufacturers Association says that that organization is studying the bill but has not yet taken a position on it. A spokesman for Merck says that the company "welcomes the legislation to control this aspect of drug abuse" and that the company believes that the wording adequately protects the interests of pharmaceutical companies. A spokesman for Squibb says that closing the designer drug loophole is necessary but that the company hopes the language of the legislation is made more precise so as not to interfere with legitimate research.

The Justice Department obviously believes that the proposed law can withstand challenges. Some lawyers are not so sure. A San Francisco lawyer who has defended a number of clients on drug distribution charges says that the law may well be "unconstitutionally vague because it defines a designer drug as a substance substantially similar to another substance. It is not clear what substantially similar in structure or effect means," he says.

That definition bothers a number of scientists. Says one: "What does 'substantially similar' mean? To me, that is almost a meaningless phrase." Another scientist points to MDMA as an example of the difficulty. MDMA is the *N*-methyl analog of 3,4-methylenedioxyphenylisopropylamine (MDA), a hallucinogen; the 3,4-methylenedioxy analog of amphetamine, a stimulant; and the α-methyl analog of 3,4-methylenedioxyphenethylamine, an antitussive. Pharmacologically, however, it resembles none of those drugs.

Henderson points out that two chemical structures that appear similar to one person, particularly a nonscientist on a jury, may well appear dissimilar to another person. "I think it will produce a field day for the lawyers," he says.

The scope of the designer drug problem is a matter of some debate. The problem so far has remained confined to California, DEA's Sapienza points out. "I personally don't think that many people are involved right now," he says. "I think that if we use our enforcement arm to prosecute those individuals, we will do a lot to wipe it out. I do not see it as a nationwide problem." Although there have been claims of overdose deaths due to fentanyl analogs in Florida and Baltimore, he says that those remain unsubstantiated.

Although agreeing that designer drugs are primarily a California problem, other observers believe that the fentanyl and meperidine analogs will start appearing elsewhere and that the underground chemists will discover other parent compounds to work their tricks on. Roberton points to PCP to make his point. When PCP, which can cause hallucinations and extremely violent behavior, first started being used in areas of Los Angeles in the mid-1960s, it was considered a bizarre California phenomenon. Its use has now spread across the country and is epidemic in some cities, Roberton says.

Based on his analysis of specimens from drug treatment centers, Henderson believes that the problem of fentanyl analogs already is widespread in California. He speculates that up to 20% of the heroin being sold in the state is, in fact, 3-methyl fentanyl, and that in some counties the figure could reach 90%. The lure of the potential profits that can be made will prove irresistible to other underground chemists, Henderson believes.

"It is hard to believe that this is not going to catch on," Langston says. "Obviously, it already has in California. These illicit chemists can make huge amounts of money, they have no problems with importation, and they cannot be prosecuted."

Langston says that a raid on a clandestine laboratory in southern California turned up a photocopied set of very simple instructions for making MPPP. "The story we got was that it had been purchased," Langston says. "I think some people have turned to selling the formulas rather than trying to make the drug themselves. That's scary because it is so easy to produce the toxin. Even a good chemist might produce some MPTP."

One aspect of those instructions provides a clue to the brutal callousness of the manufacturers of designer drugs. At the bottom of the page, Langston says, was a warning that read: "Caution. If made improperly, this may damage your clients. See attached reprint." Attached was a copy of an article on MPTP and Parkinson's disease.

Beyond new legislation, controlling designer drugs presents the same dilemmas that have confronted efforts to control other types of drugs. Roberton has been involved in prevention and drug treatment for more than 30 years, and he remains an optimist. His department, he says, has stepped up its education and prevention efforts. "If we can get to the moms and dads of this world, and the kids at an early age, then we stand a better chance."

Henderson is not so optimistic. "This is part of the evolution of drugs of abuse," he says. "It has gone from natural products to semisynthetic derivatives of natural products to stolen pharmaceuticals. Now pharmaceuticals are so tightly restricted, people are simply making their own. In 10 or 20 years, people will be using drugs that are far different from the ones available today. However, they will still be abusing drugs." □

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STATEMENT

OF

THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

BEFORE THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

ON

THE DESIGNER DRUG ENFORCEMENT ACT OF 1985

S.1437

WITNESSES: JOHN W. WHITE
PRESIDENT

JOHN M. RECTOR, ESQ.
DIRECTOR OF GOVERNMENT AFFAIRS

99th CONGRESS
1st Session

HEARING ON SEPTEMBER 18, 1985
WASHINGTON, DC

STATEMENT OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS
BEFORE THE SENATE COMMITTEE ON THE JUDICIARY

THE DESIGNER DRUG ENFORCEMENT ACT OF 1985

September 18, 1985

Mr. Chairman, Members of the Committee:

I am John W. White of Tallahassee, Florida. I serve as President of the National Association of Retail Druggists. With me today is John Rector, our Director of Government Affairs.

The National Association of Retail Druggists (NARD) represents owners of more than 30,000 independent pharmacies, where over 75,000 pharmacists dispense more than 70 percent of the nation's prescription drugs. Together, they serve 18 million persons daily.[1] NARD has long been acknowledged as the sole advocate for this vital component of the free-enterprise system.

NARD members are primarily family businesses. They have roots in America's communites. The neighborhood independent druggist typifies the reliability, stability, yet adventuresomeness, that has made our country great.

We are especially pleased to present our views to the Committee on proposed amendments to the Controlled Substances Act,[2] which will create new penalties for the manufacturing with intent to distribute, the possession with intent to distribute, or the distribution of "designer drugs", and for other purposes.

We would like to express our special appreciation to the Committee, its Chairman, and Staff for their thorough but expeditious consideration of this important legislation.

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[1] In 1982, independents filled 1,039,893,000 and chains filled 421,989,000 prescriptions of the total prescriptions (1,461,822,000) filled in the U.S. The average prescription price in 1982 for independents was $8.22 and for chains $8.29. Of the 210,493,000 prescriptions filled under the Medicaid program, chains filled 34,849,000 and independents filled 175,644,000. See American Druggist prescription survey May 1983.

[2] Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, P.L. 91-513, 84 Stat 1736, enacted 10/27/70, effective 5/1/71, is known as the Controlled Substances Act (21 USC 801 et.seq.).

When the proposals, which eventually became the CSA, were before the Congress, NARD supported this landmark reform. It was a major step forward in bringing together into a single statute the scattered and fragmented laws relating to controlled drugs.

In the intervening years, we have worked closely with federal agencies responsible for its implementation to help assure that the law and its regulations were understood by pharmacists and that our communities were protected from drug diversion and abuse. We appreciate the opportunity to continue this effort on behalf of independent retail pharmacy today.

The National Association of Retail Druggists has monitored the emergence of so-called designer drugs with an ever-increasing degree of alarm. In the 98th Congress, we strongly supported the enactment of the Drug Diversion Control Act of 1984. As relates to the subject of today's hearing, we strongly supported provisions which authorized the Drug Enforcement Administration to exercise emergency scheduling authority when necessary to address the public health hazards and complex law enforcement issues presented by the manufacture, distribution, and abuse of designer drugs.d

We were concerned that the emergency scheduling authority, as originally drafted, was far too broad, and we were pleased when the Chairman and his colleagues agreed to a modification so that only drugs not approved for medical use could be the subject of the new emergency scheduling authority. The recent exercise of the new authority by DEA in the instances of 1-methyl-4-phenyl-propionoxypiperidine (MPPP) and 1(2-phenylethyl)-4-phenyl-acetyloxypiperdine (PEPAP) demonstrates the efficacy of the modified appropach, which could in no way deny due process to the retail pharmacists we represent, who have numerous controlled substances with approved medical usefulness in their inventory.

We have supported a number of bills addressing the serious problems posed by designer drugs. We had strongly supported Senator Chiles' legislation, S.746, which would require the National Drug Enforcement Policy Board to provide a comprehensive assessment of the Designer Drug Program and make recommendations to Congress for additional legislation, and its counterpart in the House, H.R.2014, introduced by Congressman Charles B. Rangel, Chairman of the House Select Committee on Narcotics Abuse and Control.

Today, we are pleased to indicate our strong support for S.1437, the Designer Drug Enforcement Act of 1985. By providing penalties up to $250,000 or imprisonment of not more than fifteen years, or both sanctions, S.1437 will, in our view, provide an important deterrent for any person who knowingly, or intentionally manufactures with intent to distribute, possesses with intent to

distribute, or distributes designer drugs for human consumption. Additionally, we strongly endorse provisions which make these new penalties inapplicable to a person who manufactures or distributes a substance in conformance with provisions of an Approved New Drug Application or an exemption for investigational use.

Designer drugs are extremely dangerous from a health standpoint. The drugs are thousands of times more potent than the illegal narcotics presently flooding the country, and over a hundred deaths have been identified with designer drug use so far. Furthermore, these drugs have been responsible for causing long-term neurodegenerative diseases in some users. The human and medical economic costs of designer drugs are potentially devastating. It is our hope that S.1437 will be a valuable tool in the law enforcement effort to curb traffic and abuse of designer drugs.

In conclusion, Mr. Chairman, we commend you for your strong support of S.1437 and each of the co-sponsors of the legislation.[3] I am especially proud of our two Florida Senators, Mrs. Hawkins and Mr. Chiles, who have provided national leadership on the problem of designer drugs.

Again, on behalf of the Officers, Executive Committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to appear and continue to participate in the formulation of appropriate Federal drug diversion policy.

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[3] S.1437, To amend the Controlled Substances Act to create new penalties for the manufacturing with intent to distribute, the possession with intent to distribute, or the distribution of "designer drugs", and for other purposes. In the Senate of the United States, July 16, 1985 by Mr. Thurmond (for himself, Mrs. Hawkins, Mr. Chiles, Mr. Biden, Mr. DeConcini, Mr. Simpson, Mr. Cochran, Mr. Murkowski, and Mr. Specter) referred to the Committee on the Judiciary.

The CHAIRMAN. Now, Senator Biden has some questions, and some other members may have some, so we would request any member who has any questions to get those to the staff today. Then if we could leave the record open for one week, that will be an opportunity for the witnesses to answer the questions.

Senator Denton, I believe, has left some questions for the record and they will be turned over to the witnesses so they can answer those.

[Response to questions follow:]

QUESTIONS FOR AMERICAN CHEMICAL SOCIETY FROM SENATOR BIDEN

At the end of your statement you suggest an amendment to the bill that would require that both the chemical structure of a new substance and its biological effect be substantially similar to that of a controlled substance in Schedules I or II in order for it to be defined as a designer drug. In layman terms, I wonder if you could explain further how this will protect the interests of scientists and researchers and not jeopardize possible prosecutions?

ACS responses. The American Chemical Society recommends changing "or" to "and" in the definition of a designer drug in order to emphasize the designing of these substances to produce substantially similar biological effects to those of controlled substances. Thus, a designer drug would have to meet both the chemical structure and the biological effect tests. Intended as a drug of abuse, a designer drug would be specifically designed to have (1) a chemical structure substantially similar to that of a controlled substance and (2) a biological effect substantially similar to that of a controlled substance. We believe it is necessary to require that desinger drugs meet both of these tests in order to protect the legitimate production of drugs that are intended for human consumption and that have similar chemical structures to those of designer drugs, but that are designed to have the opposite or dissimilar biological effects.

For example, naloxone, a narcotic antagonist which blocks the effect of narcotics such as morphine and heroin, has a chemical structure substantially similar to both morphine and heroin, but naloxone has an opposing biological effect. Also, in legitimate chemical research, analogs of controlled substances are produced which attempt to eliminate the drugs' abuse potential. Examples are amphetamine analogs, which would be produced to retain appetite suppressant effects but to eliminate harmful biological effects contributing to abuse liability. Therefore, although the drug produced is similar in chemical structure and biological effect to a controlled substance, the drug is intended to have fewer or less serious side effects than the controlled substance.

The Society recommends the change in the definition of a designer drug because of an overriding concern for protecting legitimate chemical research. At the same time, we do not believe that meeting both definitional "tests" will unduly jeopardize possible prosecutions of designer drug manufacturers under this proposed law.

QUESTIONS FOR DR. PATRICK HANNA OR ELLIS FIELDS FROM SENATOR BIDEN

Question 1. How can the scientific community better contribute to understanding and reducing the availability of designer drugs?

Question 2. In your statement the ACS offers its scientific expertise to help solve the designer drug problems, and as you know a principal difficulty with designer drugs is analyzing its chemical content.

Does the ACS have any ideas on how designer drugs can more quickly and cheaply be analyzed in terms of chemical structure, since such information will be essential in proving violations under this Act?

ACS RESPONSE

Answer 1. The scientific community can contribute to the understanding of the problems and reduction in the availability of designer drugs by clearly instructing chemistry students in the responsibility they have as future chemists to uphold the ethics and moral standards of the profession. It is important that all students be taught the potential harmful effects that chemicals, when misused, can have. Also, it is vital that the scientific community engage in and support educational programs for all levels of school students and the general public to dispell any glamour or

attractiveness that the "designer" label of designer drugs may convey to possible users. honest, scientifically supported information, communicated at the earliest stages of this emerging problem would help to reduce the potential for designer drugs becoming a national problem of disasterous proportions.

Answer 2. There are a great number of technical problems that must be solved before disigner drugs can be analyzed more quickly and cheaply. In routine testing and screening for illicit drugs, a typical urine sample from a drug treatent center, would undergo a relatively simple, two-plate, thin-layer-chromatography [TLC] analysis, which can detect seven classes of drugs, including opiates, methadone, amphetamines, barbiturates, and cocaine. The cost of this analysis is about $3.00 to $4.00 per sample. Samples from a probation department typically would undergo a three-test system. The sample first would be screened by a two-plate TLC analysis. Samples testing positive are confirmed by an enzyme-linked immunoassay and then by gas chromatography [GC]. Only samples testing positive in all three procedures are reported as positive. Some industrial clients require gas chromatography/mass spectroscopy [MS] confirmation of positive samples, which adds about $45.00 to the cost of analysis.

For routine screening, designer drugs pose major analytical problems because the concentrations involved are well below the range of TLC. This means that immunoassay screening, which is more expensive, automatically would be required. Another difficulty is that at the present time, an immunoreagent for fentanyl is not available commercially. Also, since it is likely that GC/MS confirmation would be required for fentanyl analogs, the current cost of analysis probably would be well beyond the budgets of most drug treatment centers and many parole and probation departments.

If designer drugs do become a major part of the drug abuse scene, and if the trend is toward compounds with increasing potency, the implication for analytical laboratories is that detection sensitivity will have to increase; therefore, methodology will have to become more sophisticated, more precise, and probably more expensive. Such trends would require a significant research and development effort.

QUESTIONS FOR DR. ELLIS K. FIELDS AND PATRICK E. HANNA FROM SENATOR DENTON

1. I understand that because of the potency of these new drugs, they are very difficult to detect in the blood or urine of the user.

What special resources or equipment will drug labs need to be able to detect the presence of these drugs?

ACS response. Developing analytical assays for detection and clinical monitoring of designer drugs in body fluids is technically complex because these drugs are such potent narcotics that they are only present in very low concentrations in the blood and urine of users. Dr. Gary L. Henderson, a pharmacologist and toxicologist at the University of California, Davis, has the only laboratory in California, and one of the few in the United States, that can analyze for fentanyl analogs in body fluids. The radioimmunoassay that Henderson and his coworkers fashioned has been improved to the point where it can now detect fentanyl or fentanyl analogs at concentrations as low as 1 ng per mL or 1 ppb.

Henderson is working to develop an assay for other laboratories, but because of the technical sophistication involved, it would require a quantum jump in technology to make the analysis routine. In addition to the difficulties in detecting low concentrations of these drugs, different fentanyl analogs also may require different immunoreagents. Therefore, the specific technology has yet to be developed—as well as the special equipment and training—needed to be able to detect the presence of these drugs in body fluids.

The CHAIRMAN. I believe that completes the hearing. If so, we thank all of you witnesses for coming. We appreciate your splendid testimony.

We also appreciate your interest in this important subject. This legislation means a lot to the American people and we must pursue this matter vigorously.

Thank you very much. We stand adjourned.

[Whereupon, at 11:30 a. m., the committee was adjourned.]

APPENDIX

AMERICAN MEDICAL ASSOCIATION
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JAMES H. SAMMONS, M.D.
Executive Vice President
(645-4300)

October 4, 1985

The Honorable Strom Thurmond
Chairman
Committee on Judiciary
U.S. Senate
Washington, D.C. 20510

Re: S. 1437, "Designer Drug Enforcement Act of 1985"

Dear Chairman Thurmond:

The American Medical Association takes this opportunity to submit a statement for the record of the recent hearing concerning S. 1437, the "Designer Drug Enforcement Act of 1985."

S. 1437 would amend the Controlled Substances Act to make it a crime to knowingly or intentionally distribute, or manufacture or possess with intent to distribute a "designer drug" intended for human consumption. Violators would be subject to a fine not to exceed $250,000, imprisonment for not more than 15 years, or both. "Designer drug" is defined as a substance, other than a controlled substance, that has a chemical structure "substantially similar" to that of a controlled substance in Schedule I or II of the Controlled Substances Act or that was specifically designed to produce an effect "substantially similar" to that of a controlled substance in Schedule I or II. The prohibitions in the bill would not apply to a person who manufactures or distributes a substance in conformance with the provisions of an approved new drug application (NDA) or an exemption for investigational use (IND) under the Food, Drug and Cosmetic Act. The AMA supports S. 1437.

We believe that this legislation is needed to address the growing problem posed by designer drugs. Designer drugs are produced by "underground" chemists for abuse purposes through chemical alteration of existing controlled substances. These drugs have reportedly resulted in many deaths and numerous adverse side effects.

The bill would address the designer drug problem by closing a loophole that exists in the Controlled Substances Act. Currently, the Act authorizes the Attorney General to schedule a drug on an emergency basis for up to 1 year if it is necessary to avoid an imminent hazard to public safety. However, until a substance is actually controlled by emergency scheduling, the drug trafficker may not be in violation of the Act. S. 1437 would eliminate this loophole by making it a crime to knowingly or intentionally distribute, manufacture with intent to distribute, or possess with intent to distribute a designer drug.

The AMA is particularly pleased that the bill should in no way adversely affect legitimate chemists, drug researchers and manufacturers.

We appreciate the opportunity to express our support for S. 1437.

Sincerely,

James H. Sammons, M.D.

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